Malnutrition; can the Leeds screening tool identify haemodialysis patients at risk?

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Abstract

Background

There is global recognition of the need for early identification of those at risk of malnutrition. Nutritional screening has been advocated for systematically detecting and managing those at nutritional risk, triggering a dietetic referral where indicated. Dietetic assessment aims to minimise progression to overt malnutrition and ultimately, curtail the associated clinical and financial consequences. Patients receiving haemodialysis treatment are at increased risk of malnutrition. Generic nutritional screening tools are inherently limited in this population due to the observed variances in fluid status. There is currently no validated nutritional screening tool that is effective in this population.

Study aim

The present study aimed to test the effectiveness of the Leeds Nutritional Screening Tool (developed through pilot studies) in 140 representative haemodialysis patients.

Methodology

By means of a clinical audit, the clinical support worker tested the Leeds tool and the dietitian provided the criterion measure. A distinct feature was the inclusion of patients that were unable to fully complete answers, due to dementia, learning difficulties and a language barrier.

Findings

Risk of malnutrition was evident in 49% of the Leeds sample. The Leeds tool showed good diagnostic accuracy (95%) with sensitivity and specificity comparable with other National Health Service tests. In turn, these results suggest that patients would be appropriately signposted for dietetic assessment, without wasting finite resources. Component analysis showed that the tool was well-balanced with a combination of objective and subjective measures and that it could be simplified by removal of a question on appetite, without affecting performance. Reliability testing was achieved by patient self-completion and by a nurse, both of whom produced consistent results

with the clinical support worker. The tool was evaluated to have good practical acceptability amongst users.

Conclusions

This research suggests that the Leeds tool can identify patients at risk of malnutrition, fulfilling the requirements needed to consider local implementation, alongside appropriate staff education. This research provide a sound framework for the development and testing of nutritional screening tools, in a field of variable study quality. It is hoped that the results will contribute to the wider audience, with further research needed to assess tool transferability amongst dialysis units.

Keywords: haemodialysis, nutritional screening, malnutrition

Declaration

‘I hereby declare that the work contained herewith is original and is entirely my own work. It has not been previously submitted in support of a degree, qualification or other course’

Signed

Dated

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List of abbreviations

Abbreviation	Meaning
BAPEN	British Association of Enteral and Parenteral Nutrition
BDA	British Dietetic Association
BMI	Body Mass Index
CSW	Clinical support worker
DCJ	Dietetic clinical judgement
DI	Dietary intake
ESRF	End Stage Renal Failure
H_0	Null hypothesis
H_{1-4}	Alternative hypothesis
HD	Haemodialysis
KDOQI	Kidney Disease Outcome Quality Initiative
LST	Leeds Nutritional Screening Tool
LTHT	Leeds Teaching Hospitals Trust
MUST	Malnutrition Universal Screening Tool
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
N/S	Nursing staff
NS	Nutritional screening
NST	Nutritional screening tool
PA	Physical appearance
RA	The UK Renal Association
SGA	Subjective Global Assessment
UK	United Kingdom

Glossary of terms

Terminology	Meaning
Albumin	A protein in the blood which has many important roles, including keeping fluid from leaking out of blood vessels into the tissues
Anorexia	A decreased sensation of appetite leading to a poor nutritional status
Anthropometry /Anthropometric	Physical measurements of body size, proportions and functional capacity that can be used to interpret nutritional status
Assessment	Detailed evaluation of information, with the purpose of informing a conclusion
BMI	Body mass index, a weight for height numerical measurement used to determine whether a patient is a healthy weight
Cardiovascular disease	A disease that affects the heart and blood vessels
Clinical outcome	Measurable changes in health
Catabolism	Degradation of complex material to release energy
Co-morbidity	More than two diseases occurring in the same person
Criterion measure	The most superior measure available, which provides as the benchmark
Deficiency	Insufficiency of something ie. a nutrient
Dependent variable	The effect or outcome that is measured
Diagnosis/diagnostic	Identification of a condition
Dialysis vintage	Period of time since commencing dialysis
Dietitian	A registered expert in the field of human nutrition
Dietetic assessment	Completion of detailed evaluation of nutritional measures by a dietitian
Dietetic clinical judgement	The balance and interpretation of the information gained from a dietetic assessment by a dietitian
End stage renal failure	The failure of the kidneys to function normally, as a result of differing

	causes. Dialysis or transplant is required to sustain life
Gastrointestinal	The digestive system related to the stomach and the intestine, that is involved in consuming, digesting, absorbing and expelling nutrients
Haemodialysis	A medical treatment for end stage renal failure, using a haemodialysis machine to clean the blood of toxins and surplus fluid
Hypermetabolism	An increased rate of activity within the body
Immune function	The body's defence system against disease and infection
Independent variable	The items being changed, which may effect the dependent variable
Inflammation	The body's response at a cellular level in trying to protect against infection and to initiate the healing process
Malnutrition	A condition resulting from eating too little or too much of certain nutrients, with adverse clinical outcome attached
Metabolic disturbance /derangement	Where the body's internal environment is unstable
Multi-disciplinary	A team of health professionals, which can comprise of doctors, nurses, dietitians, pharmacists, physiotherapists
Nutritional indices /markers	Measures that in combination can be used to determine nutritional status
Nutritional intervention	A care plan aimed at helping to improve the nutrition related problem
Nutritional screening	A series of questions that are simple and quick to complete by a nurse or a clinical support worker to identify the risk of malnutrition
Nutritional screening tool	The framework of questions or variables asked during nutritional screening, which has a care plan that contains different dietary recommendations (including a referral to the dietitian where indicated)
Objective	An item that is measured within distinct categories, that has boundaries and is not influenced by opinion

Pathogenesis	The process that causes the disease
Reliable or reliability	Consistent results when completed by others
Renal	The kidney system which controls toxins, PH and fluid status
Sensitivity	The ability of the test to correctly identify disease
Subjective	Based on opinion, not specific measurements
Subjective global assessment	An assessment tool that uses several objective and subjective nutrition related parameters to aid evaluation of malnutrition risk
Specificity	The ability of a test to correctly identify there is no disease
Target weight	The goal weight for the end of dialysis, at which the body is thought to be at normal fluid balance
The UK Renal Association	The UK expert panel of renal doctors and scientists
Transferability	The extension of findings for transfer to another context or setting
Uraemic	The build-up of urea in the blood, as the kidneys are failing and this can cause nausea, vomiting and taste changes
Valid/validity	The measure is well-founded and measures what it is supposed to
Variable	A determinant or an item that is thought to be of importance
Variance	A measure of the variation

Malnutrition; can the Leeds screening tool identify haemodialysis patients at risk?

1.1 Defining malnutrition

As a result of the complex nature of malnutrition there is no universally accepted definition, despite its prevalence as a public health concern. The British Association of Enteral and Parenteral Nutrition (BAPEN) offer suggested terminology for malnutrition (as undernutrition) as "…a state of nutrition in which a deficiency…of energy, protein and other nutrients causes measurable adverse effects on tissue/body form (body shape, size and composition) and function and clinical outcome." (2003, p.8).

Without a consensus on definition, agreed diagnostic criteria for malnutrition and those at risk of malnutrition are also lacking, including anthropometric, biochemical and clinical indices (Kovesdy & Kalantar-Zadeh, 2012). Three core nutritional risk variables that contribute to the identification of malnutrition risk have been recognised (BAPEN, 2000; National Institute for Health and Clinical Excellence [NICE], 2006). These centre on body weight; a weight for height measure (Body Mass Index, [BMI]) and a calculated percentage of unintentional weight loss and also dietary intake (DI). Specialist dietetians are required to quantify and assess the functional, medical and nutritional measures to determine risk of malnutrition and in turn put treatment plans in place.

Despite the complexities of defining and diagnosing malnutrition, the adverse effects of malnutrition on 'every system and tissue of the body' (NICE 2006, p.54) are well documented. These may include altered physiological and psychological responses, such as; diminished immune function, impaired wound healing, organ dysfunction, metabolic disturbances and altered mental states (BAPEN, 2000; NICE, 2006). Malnutrition can cause ill-health and also be a

consequence of it (BAPEN, 2003). In practice there is a vicious circle, Figure 1.1, whereby ill-health can fuel nutritional depletion, which exacerbates and prolongs the clinical condition.

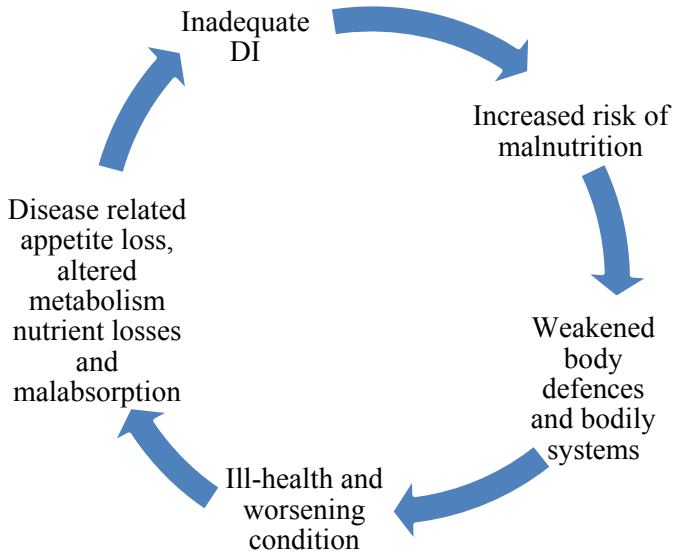


Figure 1.1 Relationship between nutritional status and ill-health

1.2 The cost of malnutrition

Over 3 million patients in the United Kingdom (UK) are estimated to be at risk of malnutrition (BAPEN, 2009), costing over 10% of national health expenditure (BAPEN, 2005, p.34), at £13 billion per annum (BAPEN, 2009, p.2). As the risk of malnutrition and clinical adversity progresses (described in Figure 1.1) predictably, so do the financial penalties. BAPEN (2005, p.22) estimate that patients at medium and high risk of malnutrition cost healthcare resources nearly double that of those at low risk (a difference of over £1,500 per annum per patient). Lim et al. (2012) extends clinical concern, demonstrating a four-fold increased risk of mortality at 1 year ($p<.001$) in malnourished patients, as diagnosed by an expert dietitian. A proactive, co-ordinated and timely approach for identifying, managing and monitoring the endemic problem of malnutrition is therefore of paramount importance to reduce patient, medical and financial burden (NICE, 2006).

1.3 A way forward

Screening is an integral process in the National Health Service (NHS) for the evaluation of many medical parameters (such as risk of fever, falls and dementia). Screening involves the nursing staff (N/S) or the clinical support worker (CSW) to complete a series of quick and simple questions relating to clinical risk variables for the systematic detection of those at risk (Arrowsmith 1999; Ferguson, Capra, Bauer, & Banks, 1999). The associated scoring system can then facilitate the action required and direct finite resources appropriately (Bennett et al., 2012). The identification, management and monitoring of those at risk of malnutrition through nutritional screening (NS) and associated care plans, seen in Figure 1.2, are supported by an abundance of UK government standards and specialist groups (British Dietetic Association [BDA], 1999; Kondrup, Allison, Elia, Vellas & Plauth 2003; NICE, 2006).

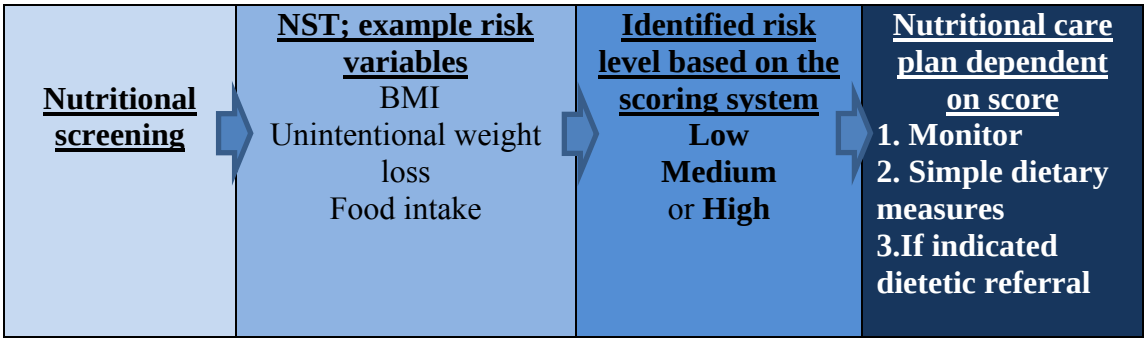


Figure 1.2 Nutritional screening overview

Nutritional care has been identified as potentially the fourth biggest NHS cost saving (BAPEN, 2010, p.3), with an effective NST being at the very core of this. Unfortunately there is not one specific nutritional screening tool (NST) that is valid in all patient groups (BDA, 1999; Van Bokhorst, Guaitolo, Jansma & Vet, 2013).

1.4 End Stage Renal Failure

Perhaps the strongest argument for NS is within patients with chronic conditions, such as those with end stage renal failure (ESRF), where malnutrition is described as 'one of the most prevalent complications' (Yamada et al., 2008, p.106). Upto 40% of patients receiving haemodialysis (HD) treatment are at risk of malnutrition according to the UK ESRF specialist

body (The UK Renal Association [RA], 2010), which is extended to 75%, by the expert European consensus panel (Fouque et al., 2008, p.392). With the acknowledgement that the HD population is currently over 23,000, increasing by 2.3% since 2011, the scale of concern can be appreciated (RA, 2013).

As a result of declining kidney function leading to ESRF, the patient requires HD to clean the blood of unwanted toxins, to help restore normal fluid balance and to correct metabolic disturbances. The patient needs to attend the dialysis unit three times a week for this to happen. The altered metabolic processes and symptoms associated with HD, along with elevated nutritional requirements make this a nutritionally fragile population.

The consequences of malnutrition-related clinical sequelae in ESRF mirror those seen in the general population, as concluded by multiple authors (Kidney Disease Outcomes Quality Initiative [KDOQI], 2000; Kovesdy & Kalantar-Zadeh, 2012). Lawson, J., Lazarus & Kelly (2001), for example found that malnourished patients with ESRF had increased hospital admissions (23%) over 12 months (p .001). Likewise, de Mutsert et al. (2009) noted malnutrition as an independent predictor of morbidity and mortality within their large ESRF sample (n=1601) of malnourished patients, reporting a dose dependent relationship with severity of malnutrition.

Nationally, RA (2010) and internationally, KDOQI (2000), support NS throughout the course of HD, for the identification of those needing dietetic assessment. There is currently no validated NST for the HD population (KDOQI, 2000; RA, 2010). Generic NSTs have a reduced diagnostic accuracy in patients with altered fluid balance, such as those with ESRF (RA, 2010). This is because fluid can bias the interpretation of core nutritional indices which NSTs rely upon (such as weight, weight loss and BMI) (Visser, Dekker, Boeschoten, Stevens, & Kredict, 1999).

1.5 Summary

This section has endeavoured to identify the serious issue of malnutrition and the importance of early screening with prompt dietary management, in an attempt to reduce the possibility of malnutrition, manage resources and improve clinical outcomes. HD patients are at

an increased likelihood of experiencing malnutrition and the Leeds Teaching Hospital Trust (LTHT) has identified the need for an effective NST, driven by NICE, (2006) and RA (2010). Consequently, the Leeds Nutritional Screening Tool (LST) has been developed and piloted (see Appendix 1, 2).

Primary study aim

The primary aim of this audit was to test whether the senstivity of the LST is consistent with dietetic clinical judgement in identifying HD patients at risk of malnutrition.

The literature review

At the outset of this chapter the complex pathogenesis of malnutrition in ESRF will be outlined, alongside observed rates of risk of malnutrition. The requirements of an effective NST will be detailed, setting the context of this study. Two tools will be presented as examples; Malnutrition Universal Screening Tool (MUST) and the Subjective Global Assessment (SGA). This literature review will consider important data relating to the testing of these tools, focusing on UK and European studies. Despite the wealth of information within the field of malnutrition, the specific aspect of malnutrition within HD has been relatively overlooked. Nonetheless, lessons can be drawn from the content and testing of these tools, which has informed this research (Appendix 2).

2.1 Pathogenesis of malnutrition in the HD population

Malnutrition within the HD population is due to a complex interplay of disease and non-disease specific risk variables, with the underlying principles illustrated in Figure 2.1.

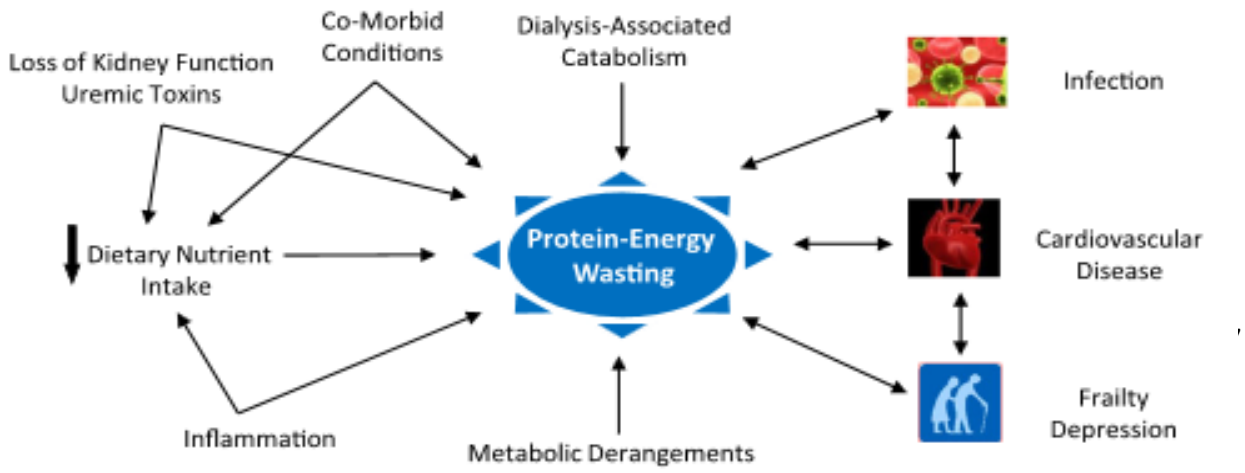


Figure 2.1. Pathogenesis of malnutrition in HD (with permission from Carrero et al., 2013, p.78)

The identified risk variables in ERSF, in Figure 2.1, provide a literary framework for research into the effect of each determinant on progressive anorexia, which are detailed under two main processes; increased nutritional requirements and reduced DI.

2.1.1 Increased nutritional requirements. The following information describes at the metabolic level how HD treatment predisposes patients to malnutrition.

Dialysis associated catabolism. Although relatively unexplored, the relevance of dialysis associated losses are identified by Neyra et al. (2003) stating that energy expediture increases upto 20% (cited by Carrero et al., 2013). Furthermore, Ikizler and Hakim (1996) report a two-fold increase in protein requirements due to HD, although this work is nearly two decades old it remains consistent with current therapeutic guidelines (BDA, 2011). Water soluble vitamin losses are also evident (RA, 2010).

Metabolic derangements. ESRF is associated with inflammation, hypermetabolism and hormonal derangements and consequently, protein catabolism is induced, heightening nutritional needs (Stenvinkel, Heimburger, Lindholm, Kaysen & Berdstrom, 2000).

2.1.2 Reduced DI. Malnutrition risk is heightened due to HD related effects on DI. Lawson, J. et al. (2001) linked necessary dietary potassium and protein restriction with malnutrition, however they failed to see similar trends with other dietary restrictions and this may be due to a limited sample size (n=50). Confusion over dietary restrictions and patient over-restriction can also limit DI in practice.

Loss of kidney function and Uraemic toxins. The importance of effective dialysis, to remove toxins and excess fluid is demonstrated by Galland et al. (2001), whereby on receiving good dialysis there was an increased intake of 13% and 24% in energy and protein (cited by Locatelli et al., 2002). Due to the effects of HD, about 60% have a diminished appetite, with fluctuating appetite and gastrointestinal symptoms commonly experienced (Kalanatar-Zadeh et al.

2004; Lopes et al., 2007). This can be due to HD issues of low blood pressure, blood loss and anaemia.

Medical conditions. Co-morbidities, such as cardiovascular disease and diabetes are highly prevalent within the HD population, up to 70% in the study of Taiwanese patients by Tsai, Lu and Chang (2009). This is in part due to the ageing HD population, an average of 66.9 years (RA, 2013). Although inconclusive, some authors correlate these conditions with malnutrition (Carrero et al., 2013; Quershi et al.,1998). Malnutrition risk may be heightened in the ageing HD patients if illness dictates hospitalisation; fasting for investigations, fatigue, anxiety and altered HD and also if there is increased dependence on social support (Carrero et al., 2013).

Frailty and depression. Locatelli et al. (2002) recognise that psychological distress, depression and poor quality of life are associated with HD. Kalantar-Zadeh, Block, McAllister, Humphreys & Kopple (2004) report that there is an inverse correlation between quality of life scores and appetite, within their sample of 124 HD patients (p .001). This sentiment that low mood can impair DI is reflected in clinical observation.

Although written two decades ago Ikizler and Hakim (1996) aptly conclude a variety of authors work, terming malnutrition in the HD setting as a co-morbid condition in its own right.

2.2 Rates of risk of malnutrition in the HD population

Although much work has been done within the field of malnutrition, particularly with regards to incidence and prevalence, comparing studies is difficult due to the absence of a diagnostic framework (see Section 1.1). Furthermore, there are limited nutritional studies with adequate methodological control, broad sample sizes and quality reporting in the HD environment (Elia, Zellipour, & Stratton, 2005). This has led to inconsistencies in the reported rates of risk of malnutrition in HD, from 18% to 75% (Fouque et al., 2008). An illustrative example is based on the frequently cited Dutch study by Visser et al. (1999), in which 36% of ESRF patients were malnourished (using SGA, see later). This was however based on 13 patients receiving HD, within a sample of 2 different dialysis modes and research was 16 years ago. With cultural,

historical and environmental changes over this period, results hold limited value and applicability to the UK HD population. A seven year multicentre study in a larger Dutch population (n=1601) observed lower rates of risk of malnutrition (28%), however results were constrained by the lack of quality reporting on methodological control across the 38 centres involved and with baseline differences in ethnicity to the UK (with 92% of the sample white) (de Mutsert et al., 2009).

In 2010 RA highlight the lack of sound research for numerically defininig risk of malnutrition within the UK, by quoting rates obtained from a review written two decades ago (Ikizler & Hakim, 1996). Current LTHT data is consistent with this however, at 43%, identified by the dietitian within a small patient number (N=14, see piloting summary in Appendix 1).

Although exact rates of malnutrition are not confirmed, the nutritional vulnerability of the HD population, 500 patients locally at LTHT and over 23,000 patients nationally (RA, 2013), cannot be disputed.

2.3 Identifying an NST for the HD population

Despite the overwhelming research placing NS as a high priority requirement in the HD setting (KDOQI, 2000; Locatelli et al., 2002; RA, 2010), failings exist in the development and testing of NSTs due to key determinants, in Table 2.1, often being overlooked (Elia et al., 2005).

Table 2.1

Established NST determinants, adapted from the BDA (1999, p.3)

Tool requirement	Rationale	Comment
Evidence based	NST should incorporate defined nutritional principles	Must be appropriate for the patient group and setting
A powered study	A powered study to avoid type 1 and type 2 statistical error	Must be representative of the intended population
Valid	Sensitivity- able to correctly detect patients at risk (or those malnourished) Specificity- able to correctly detect patients who are not at risk	The criterion measure must be the most superior measure available for identifying risk of malnutrition, to test against the NST
Reliable	NST should be tested by the intended users	Differences between users may be relevant for future implementation

Practical	Primarily it must be user-friendly and appropriate for the intended setting	User and patient feedback must be collated to consider improvements

Jones, J. (2002) in her comprehensive review of 44 papers, headlines the particular criticisms of NST testing in ESRF patients to be a lack of justification of NST derivation, use of unsubstantiated nutritional parameters as the criterion measure and insufficiency in study details.

The criterion measure within a study sets the benchmark for its quality, providing study outcomes based on comparison with the test variables (Elia & Stratton, 2011). Deviation from the most superior measure available, with unsubstantiated criteria, questions the validity of the study (Jones, J., 2004c). Cooper et al. (2002) for example, used total body nitrogen as the criterion measure, of which Desbrow et al. (2005) questioned the reliability within overweight patients. The conclusion by Cooper et al. (2002) that a diagnostic tool (SGA) holds low sensitivity with malnutrition is therefore of limited value. Similarly, Yamada et al. (2008) use a diagnostic tool based on albumin levels as the criterion measure and with study results they discredit 5 NSTs, which is inappropriate when it is widely accepted that albumin is an insensitive marker of nutritional status (Locatelli et al., 2002; KDOQI, 2000; Quershi et al., 1998). Furthermore, they excluded malnourished patients and therefore the sample was not representative.

Dietetic clinical judgement (DCJ) based on expert dietetic assessment (Table 2.2) is the acknowledged criterion measure in NST validation, with the absence of consensus diagnostic measures (Bennett, Breugelmans, Meade & Parkhurst, 2005; Van Bokhorst et al., 2013).

Table 2.2

Features of dietetic assessment, adapted from the BDA (1999) and Gower (2002)

	Dietetic assessment
1.	Diet history taking to assess DI
2.	Nutritional requirements based on therapeutic guidelines and evidence based practice
3.	Weight history (as percentage weight loss and BMI)
4.	Anthropometry to examine physical measurements of body composition
5.	Subjective Global Assessment (SGA), a scoring technique to evaluate key

	nutritional risk variables and physical appearance measures
6.	Social factors
7.	Medical information (including previous medical history, concurrent illness, medications and treatment)

By ignoring the underpinning NST principles (Table 2.1) introduction of an unvalidated NST may not only inappropriately worry the patient that they are at risk of malnutrition, but also waste resources by incorrectly referring patients for dietetic intervention (described by The BDA, 1999; Ferguson, , Capra, Bauer, & Banks, 1999). Oakley and Hill (2000) reported a projected 77% increase in referrals as a result of future implementation of their ill-tested NST, with bias introduced by the researcher and scoring altered retrospectively. This estimated increase is a significant demand on dietetic resources and therefore the results highlight that an NST needs to be sensitive (correctly identifying those at risk) and specific (correctly identifying those not at risk), otherwise resources may be unduly exhausted.

Regardless of the flaws within the current evidence base of NST development and testing, lessons can be learned (Jones, J., 2004a). The following critique of two frequently studied tools has informed previous LST piloting and the current study (Appendix 1).

2.4 Tool 1 Malnutrition Universal Screening Tool (MUST)

MUST (in Appendix 3a) is advocated by the NHS as the generic NST of choice for patients admitted to hospital. MUST is based on a sound theoretical framework, having content validity, with robust objective measures and created by a panel of multi-disciplinary experts (BAPEN, 2003). It has tested favourably by multiple authors on multiple occasions, in mixed hospital patient groups, of differing demographics and with varied co-morbidities (Kondrup, et al., 2003; Van Bokhorst et al., 2013). Correspondingly, 82% of hospitals surveyed in the UK have adopted this validated NST (reported by 205 hospitals, BAPEN, 2014). Unfortunately, this well designed and tested NST is not valid in the HD population, with many studies simply omitting representation of this patient group (as seen Elia et al., 2005).

2.4.1 Testing MUST in ESRF. Bourke, Mafrici, Livesey, Peacock and Roe (2010) demonstrated MUST insensitivity in ESRF patients, reporting that DCJ identified more than twice

as many hospital patients to be at risk of malnutrition than MUST (43 compared with 18). Similarly, Lawson, C., Campbell, Dimakopoulos and Dockerell (2012) found in their study of 190 patients, MUST only had 53.8% sensitivity and 78.3% specificity to the criterion measure, provided by a dietitian,. Comparably, many NHS diagnostic tests have a sensitivity and specificity level of 70% (to be discussed in Section 5.4.1), therefore showing MUST's impaired performance in identifying those ESRF patients at risk. The results may have been skewed in Lawson, C. et al. (2012), as there was missing data in 54/276 patients.

In the HD setting, the suboptimal performance of MUST is transferred, shown by Fisher et al. (2011) with MUST having a sensitivity of 31% and specificity of 95% in a sample of 65 handpicked HD patients thought to be at risk of malnutrition, identified by a N/S. Equally, Hyam, Jackson, Hart and Engel (2010) reported that MUST failed to identify 32 HD patients as malnourished, as compared with SGA (p= .05).

The main reason for the observed insensitivity of MUST in HD patients is due to its inflexibility in patients with altered fluid balance. Fluid status in ESRF can range from severe fluid overload to dehydration as a result of reduced (or completely absent) urine output and due to fluid removal on HD (one to four kilograms, three times a week). Without appropriately adjusting a patient's weight for fluid weight, BMI and percentage weight loss calculations can lead to inaccurate conclusions about nutritional status. BMI and percentage weight loss appear as two thirds of the contents of MUST and therefore MUST is significantly undermined in the HD setting. This limitation is acknowledged by its authors and consequentially, RA conclude that due to this potential fluid bias objective measures using body weight (BMI and percentage weight loss) require an 'extra level of interpretation' (RA, 2010, p.10).

2.4.2 The content of MUST. Despite the concerns of using weight calculations in this setting, BMI and percentage weight loss, research suggests that they remain as core nutritional risk variables for inclusion in an effective HD NST. Campbell, Bauer, Ikehro and Johnson (2013) reported BMI as a predictor of poor outcome (p .001) and although this is an anticipated result, the

study lacked the acknowledgment of whether flesh weight had been appropriately adjusted for and therefore the conclusions may have been diluted. Similarly, Campbell and Maclaughlin (2010), reported that percentage weight loss correlated with mortality risk (by three-fold, p= .02), even after analysis adjustment for disease severity. Campbell and Maclaughlin (2010) appropriately use the goal weight a patient is at the end of dialysis, 'target weight,' for their nutritional calculations (consistent with Quershi et al., 1998). Target weight at the end of dialysis is the most appropriate weight to use, based on clinical practice, as this has been set by the renal multi-disciplinary team as the weight at which the patient is not carrying excess fluid. Inaccuracies can be introduced even with these objective measures having best guess adjustments, due to the complexities involved in estimation and therefore qualitative weight change also provides value (Ferguson et al., 1999; Unpublished data in Appendix 1).

The third question from MUST incorporates acute illness and so in a population with chronic ESRF this is not principally relevant and may also contribute to the reduced accuracy seen. Janardhan et al., 2011 found that a question about medical condition and co-morbidities led to reduced NST accuracy due to the reliance on patients' memory and this was consistent with previous LTHT pilot work (Appendix 1).

2.4.3 Other relevant MUST considerations. MUST is praised for its practical acceptability, as observed by Stratton, Cawood, Rust, Walters, & Elia (2010) scoring highly on ease and quickness of use (96% and 98%, respectively) with 205 patients attending a clinic appointment, of which the mean age (55 years) was comparable to those on HD. This format is thought not only to reduce the time burden for staff of overcomplicated and unnecessary questions, but in turn improve compliance (BAPEN, 2003).

2.5 Tool 2 Subjective Global Assessment

The SGA tool (Appendix 3b) and its contents have been acknowledged by high level national and international committees, such as KDOQI (2000) and RA (2010) to be of value in the HD setting. SGA is however an assessment tool, comprehensive and detailed and can form as part

of DCJ, alongside other nutritional parameters, in Table 2.2 (Steiber et al., 2004). By its very definition then, SGA contradicts the ethos of an NST; quick, simple and for those without nutritional qualification, illustrated in Figure 1.2.

Despite its definition, there are questions over the transferability of SGA to the current HD population for the purpose of assessing risk of malnutrition (KDOQI, 2000; Van Bokhorst et al., 2013). These concerns are based on the origins of SGA three decades ago, created by a group of clinicians for use in a surgical population and for the purpose of predicting clinical outcomes (Detsky et al., 1987). Furthermore, there are currently eight various forms of SGA, which makes comparing studies difficult, particularly as tool modifications are described in Campbell, Ash, Bauer and Davies (2007) and Steiber et al. (2004) as unsubstantiated and inadequately tested. Kalantar-Zadeh, Kliener, Dunne, Lee & Luft (1999) for example, developed a seven tier scale of an older three scale model, to allow for an expansion in risk categories. They inappropriately discounted the three scale SGA, as the seven tier compared better with an unrecognised criterion standard (anthropometric and biochemistry). The study is further limited by its small sample size (N=40) and thus confirms that SGA should be used by an expert in combination with other measures (Jones, C., Wolfenden & Wells, 2004).

2.5.1 Testing of SGA. Despite the numerous versions, the subjective thread of SGA is advocated by KDOQI (2000) and RA (2010) as being of primary importance in the HD population due to the fluid shifts causing inaccuracies associated with objective data (weight loss and BMI) (Section 2.4.1). Enia, Sicuso, Alati & Zocalli (1993) provide an illustrative example, reporting that the subjective evaluation of physical appearance (PA) correctly identified those at risk of malnutrition, whereas percentage weight loss failed to identify them, presumably as the authors failed to adjust flesh weight for fluid bias. PA is found to be a particularly difficult element of subjective assessment in the ageing HD population, as with functional ability, as SGA demands the categorisation of solely nutrition-related decline and not age related alterations (Johansen et al., 2013). This challenge is acknowledged by de Mutsert et al. (2009) who although provided

workshops for researchers, decided to alter questions relating to PA due to concerns over its inaccuracy. LST piloting (Appendix 1), although based on only 28 patients, showed that PA, unlike functional capacity, is of benefit (and is recommended by RA, 2010). Bryan, Jones & Russell (1998) explain that despite the variability in subjective evaluation of PA, accuracy is improved with staff that are in frequent contact with their patients, as is the case in HD.

Subjectivity, by its very nature puts SGA at a disadvantage in terms of its precision and so it is imperative to test the NST in conditions that mimic the perspective of the future user, their nutritional knowledge and their relationship with the patient before NST implementation (Locatelli et al., 2002). Campbell et al. (2007) describe that of 14 studies involving SGA, only one study had an N/S as the administrator and instead dietitians or physicians were commonly seen, as is the case in Campbell et al. (2013), thus garnering results that are not fully applicable. Fisher et al. (2011) considered patient self-completion, which is important in the current NHS climate of shared care, whereby patients are being empowered to be active in their own health. They reported good sensitivity, however over 50% (of 65 patients) required assistance, thus defeating the purpose of self-completion. The figure of patients unable to self-complete is higher than expected and may be a result of an older sample, although age was unfortunately not stated.

Testing SGA measurements between intended user groups (CSW, N/S and patient) is also rarely seen, with Steenson, Vivanti, and Isenring (2013) reporting only 13% (15/249) of published studies evaluated reliability. Visser et al., (1999) do assess reliability of SGA measurements between four N/S, however this was in a limited sample of 22 patients and a detailed methodology was lacking, thus further research is required.

2.5.2 The content of SGA. Despite the study limitations discussed above, SGA has been tested within the HD setting and the nutritional risk variables SGA contains may provide value in identifying malnutrition risk. SGA (in Appendix 3b) incorporates all three evidenced core nutritional criteria that are essential for an NST; BMI, percentage weight loss and DI (Fouque et al, 2008; NICE, 2006). The former 2 have been discussed in Section 2.4.2 and PA, functional

capacity and co-morbidities have been outlined in preceding sections. The remainder core nutritional risk variable DI, alongside the closely linked SGA variables, appetite and gastrointestinal symptoms will be discussed here.

Although DI and appetite are often used interchangeably, through the literature and in clinical practice, Kalantar-Zadeh et al. (2004) describe that there are important differences, as the actual amount eaten and the desire to eat, respectively. This distinction is fundamental in the HD setting, where fluctuating HD related symptoms and gastrointestinal symptoms commonly lead to a diminished and variable appetite (in 43%, Burrowes et al, 2005). These transient changes in appetite do not however necessarily affect DI and the longer term marker of nutritional status, (KDOQI, 2000; Unpublished work in Appendix 1). NICE (2006) describe that the longevity over which a reduced appetite and gastrointestinal symptoms affect unintentional reductions in DI is the primary factor for consideration. A reduced intake for 5 days or more has been suggested by BAPEN (2003, p.28) as the timeframe at which risk of malnutrition begins. Nonetheless, both reduced appetite and DI have been associated with poor outcomes, as correlated by Burrowes et al. (2005), leading to increased hospitalisation (28%) and mortality (53%). Even though these results were not statistically significant on adjustment for co-morbidities, they suggest that DI and appetite are important variables for NST inclusion.

2.5.3 Other SGA considerations. There is limited reference to the inclusion of the minority HD patient group that are unable to converse with staff, due to dementia, learning difficulties or language barrier. This patient group accounted for 6% of 275 general inpatients, with a mean age of 55 years, in the work by Cawood, Elia, Sharp and Stratton (2012). Ferguson et al. (1999) simply exclude this patient group and automatically refer them to the dietitian, regardless of their nutritional status, which ultimately may increase inappropriate referrals. Bryan et al. (1998) recommend carer involvement with NST completion where possible, although accuracy has not been tested here.

Detsky et al. (1987) and de Mutsert et al. (2009) recognise that SGA has a unique way of coping with unanswered questions, by using an averaging system for questions that are answered. Although effectiveness of partially completed SGA tools has not been comprehensively tested in this patient group averaging NST results may allow effective NS in this sensitive HD population.

2.6 Summary

This chapter has sought to map out the key issues associated with the development and testing of an NST in the challenging HD population. It is hoped that the importance of identifying those at risk of malnutrition is portrayed, alongside the realisation that if ignored risk of malnutrition will lead to overt malnutrition and associated clinical and financial repercussions. Although there is no common agreement over the definition and diagnosis for those at risk of malnutrition and there are a limited number of quality studies, the UK expert Renal Association strive to highlight the complexity of their concern. Despite MUST being over 10 years old, there remains no replacement for it, however due to its inflexibility with fluid balance it performs poorly in this population. SGA has a higher international profile, however despite adaptations it is not efficient enough as an NST, although the nutritional risk variables it contains and its scoring system may be of value. There is firm evidence to support the justification of developing and testing a new instrument for the HD setting, before considering implementation. Table 2.3 draws together the essential parameters identified from this critical appraisal, from clinical observation and previous pilot studies (Appendix 1, 2), which are required to move LST towards validation.

Table 2.3

NST validation requirements

LST	Comment
Tool aim	Highlight those at risk of malnutrition (including those that are malnourished)
Risk variables	Include a mix of objective and subjective questions. Include the 3 core nutritional criteria; weight as BMI, percentage weight loss and DI. Plus appetite and PA. Exclude gastrointestinal symptoms, functional capacity, dialysis years, co-morbidities & biochemistry
Tool outcome	Link to a nutritional care plan
Criterion measure	DCJ
Education	Provide guidance for administrators, to consider the complexities in HD
Practicalities	Test for its practical acceptability, in the future environment and with intended users (patients, CSW and N/S)
Testing and analysis	Test within a powered study and representative sample and use appropriate analysis techniques (Jones, J., 2004a).

2.7 Research objectives

1. To test the sensitivity and specificity of the LST in identifying malnutrition risk in HD patients, from a computer generated sample of convience. LST is completed by a CSW and is compared to the criterion measure of DCJ.
2. To evaluate the appropriateness of LST risk variables by assessing accuracy of incomplete tools and analysing each risk variable.
3. To assess the reliability of the LST within a subset of patients by the intended users; CSW, the N/S and the patient.
4. To collate questionnaire feedback completed by the intended users to inform the appropriateness of using the LST.

Primary hypothesis.

H_1 is that the LST will have a high level of sensitivity compared with DCJ in identifying HD patients at risk of malnutrition.

H_0 is that the LST screening tool will not have a high level of sensitivity compared with DCJ in identifying HD patients at risk of malnutrition.

Secondary hypotheses

H_2 The LST will have a high level of specificity compared with DCJ in identifying HD patients at risk of malnutrition.

H_0 The LST will not have a high level of specificity compared with DCJ in identifying HD patients at risk of malnutrition.

H_3 The LST will not be equally effective when the risk variables are not fully completed.

H_0 The LST will be equally effective when the risk variables are not fully completed.

H_4 The reliability of the LST will be equally as accurate when the tool is utilised by different users.

H_0 The reliability of the LST will not be equally as accurate when the tool is utilised by different users.

Methodology

3.1 Study design

This study was a clinical audit comparing the effectiveness of LST in identifying risk of malnutrition, with the criterion measure of DCJ, in an HD patient group.

3.1.1 Dependent and Independent variables. The dependent variable was the criterion measure of DCJ, a non-validated standard to identify malnutrition risk. This is in keeping with the work by Desbrow et al. (2005), who considered SGA as the dependent variable. DCJ was based on specialist skills obtained through registered dietetic training, evidence based practice and clinical experience of one renal specialist dietitian ('the researching dietitian'), the author. DCJ encompassed the evaluation (Appendix 4) of current patient multi-disciplinary records, dietetic records and the LTHT computer system and assessed;

- Objective weight data; flesh weight, body composition, BMI and weight loss
- Recent assessment; nutritional requirements, DI, anthropometry and SGA
- Medical information; biochemistry, dialysis details and medical history
- Social information; mood, confusion and neglect

Fifty two patients required direct contact by the dietitian due to insufficient detail (or if the last assessment was over two months ago). Oakley and Hill (2000) and Weekes, Elia & Emery (2004) have a similar approach for DCJ scoring and provided guidance for this study. On balancing these risk variables the dietitian allocated a score on the same malnutrition risk category continuum as the independent variable (as encouraged by Jones, J. 2004a), to be discussed in Section 3.1.2.

The independent variable was the LST (in Appendix 2), tested in paper format which incorporated six risk variable questions, of which four were subjective and two were objective. Each question had a numerical score attached to signify malnutrition risk. LST was completed by one HD based CSW, one HD based nurse and 13 patients. The overall risk score was generated as

a mean from the questions answered and in turn corresponded to a risk category (discussed in 3.1.2).

3.1.2 Outcome measures. Table 3.1 illustrates how the DCJ and LST numerical scoring system converted to a malnutrition risk category. For LST, the numerical score was a mean result and so if this figure fell between two risk categories, the traditional cut-off of greater than 0.5 was used to round up the score to the next risk category (as illustrated in the second row of Table 3.1).

Table 3.1

Risk category continuum

Score category	**1**	**2**	**3**	**4**
Including ranges	**1-1.4**	**1.5-2.4**	**2.5-3.4**	**3.5-4**
Risk category	No	Low	Mild and moderate	Severe

Categorisation along a continuum such as this is derived from theoretical frameworks associated with MUST and SGA, as detailed by BAPEN (2003) and Steiber et al. (2004)and has been tested through previous LST piloting (Appendix 1). For the purposes of the audit a score of 3 plus indicated 'at risk' of malnutrition and stipulated a dietetic referral, established by the LTHT renal dietetic team. A score category below 3 indicated limited clinical risk (‘low risk’) and 'no risk' and indicates no referral is required, just future monitoring.

3.2 The population and subjects

3.2.1 Ethical approval. This study did not require NHS ethical approval (see Appendix 5), as it falls under the NHS definition of service development (NICE, 2002). It has received ethical approval from the University of Chester (see Appendix 5). There was a great emphasis placed on following the Health and Care Professions Council standards of conduct (2013). There was also peer approval within the wider renal team (see Appendix 5), with peer checking at regular intervals to monitor compliance with the Caldicott Principles (as summarised by NICE, 2002).

Each subject consented using the patient information sheets and written consent forms (see Appendix 6). In 4 patients who were unable to converse or consent, a carer who attended the dialysis unit with the patient, translated and consented to take part on their behalf. In 9 patients, where there were no carers available, the LST was completed in the patients' best interest (with renal consultant permission). The subjects did not receive reimbursement for their participation.

3.2.2 Sample size calculations. The sample size was estimated as N=139 using calculations by Jones, J. (2004a) based on the statistical analysis required for NST testing (see Appendix 7 for further justification). Other relevant researchers have cited this author (Campbell et al.,2007) and support this analytical technique (Tsai et al., 2009). CSW and dietetic research time was agreed by the renal and dietetic team in order to facilitate reaching the desired sample.

Reliability testing was completed by two groups; an N/S and a patient sample, as both are intended future users (Section 2.5.1). N/S involvement was set at a clinically feasible amount, at 10% of the sample (14 patients), as funding was not granted and so involvement formed as part of clinical duties. A figure of 10% (n=14, 1 declined) was decided for patient self-completion, based on a balance between feasibility, envisaged patient burden and the small number of patients who are able to self complete (at 12% from pilot studies, Appendix 1). These figures were also guided by Ferguson et al. (1999) and Lawson, C. et al. (2012) who carried out NST reliability testing in 8% of their sample (in 32/408 and 23/276 respectively).

3.2.3 Study sampling. LST efficacy was tested in the target population, Table 3.2.

Table 3.2

Study sample criteria

Inclusion criteria	Rationale
All adult patients with a diagnosis of ESRF undergoing HD for more than 3 months	The 3 month cut-off is consistent with the study by Campbell et al. (2013) and de Mutsert et al. (2009), allowing for an appropriate period of adjustment. HD patients are standardly assessed by the dietitian on starting dialysis, without the need for NS.
Daytime HD patients	Logistical reasons.
Satellite and main site	Representative sample of stable and less stable HD patients.

Exclusion criteria	Rationale
HD patients in hospital	These patients are in a different clinical environment
Patients receiving other modes of dialysis therapy	This is a separate population segment, with a different treatment mode and thus not the intended population

3.2.4 The sample population defined. The LTHT renal computer system generated a report that identified eligible patients from a sample of convenience (N=156). The report randomly ordered the patients into shifts, for ease of use and then allocated each patient a number.

16 patients failed to complete and this was due to hospital admission (n=3), death (n=7), transplant (n=3) and declining to take part (n=3). The attrition rate of 1% is similar to NST testing seen in the pilot study (Appendix 1) and in the 2012 work by Bennett et al. At the end of data collection, numbers recruited totalled 140, meeting sample size requirements. With a low number of patients failing to complete, the study sample (see Table 3.3) was thought to be representative.

Table 3.3

Sample characteristics (N=140)

Characteristics	Results
Dialysis	Morning HD=53% (74/140), Afternoon HD=47% (66/140)
	Three times a week dialysis=96% (remainder were twice a week)
	Mean time on dialysis=4.2 years (± 5.2)
Demographics	Mean age=62.2 years (± 16.1, range 19-89)
	Male=64% (82/140), female=39% (38/140)
	White=74%, Asian=14%, Black=12%
Medical	More than one co-morbidity=66% Diabetes=17% Smoker=20%
Nutritional	Target weight=65.7 Kg (19.3kg-89.6 Kg) BM=27.7 Kg/m^2 (± 6.7 Kg/m^2) Percentage weight loss=1.4 % (± 3.4%) over 3 months.

3.3 Procedures

3.3.1 A: Standardised protocol. At the outset of the study, the researching dietitian provided one separate education session for the CSW and the N/S (Appendix 8), in keeping with de Mutsert et al. (2009) and Weekes et al. (2004). The aim of the session was to provide guidance on ethical considerations and to aid consistency in methodological approach as outlined in Table 3.4 (and Appendix 8).

Table 3.4

Standardised protocol for the CSW and N/S

Step 1	*Completion order*	On gaining consent (Appendix 6), the subjective questions (A to D) were asked first, to reduce user bias of knowing the objective measures.
Step 2	*Objective data*	Obtaining electronic objective weight and height data was in keeping with Gower, (2002) (Appendix 8, handout 2).
Step 3	*Choosing an appropriate risk score*	The user's clinical judgement and their interpretation of patient responses were required for choosing the appropriate risk level (of which a standard technique was encouraged, in Appendix 8). If unclear of the appropriate answer, questions were left unanswered.

3.3.2 Audit data collection. The data collection period was over 11 weeks, from May to August 2014. Figure 3.1 provides an overview of the audit, detailing the order and timings of both arms of the study, including the interaction between parties and what happened to the patient at each step.

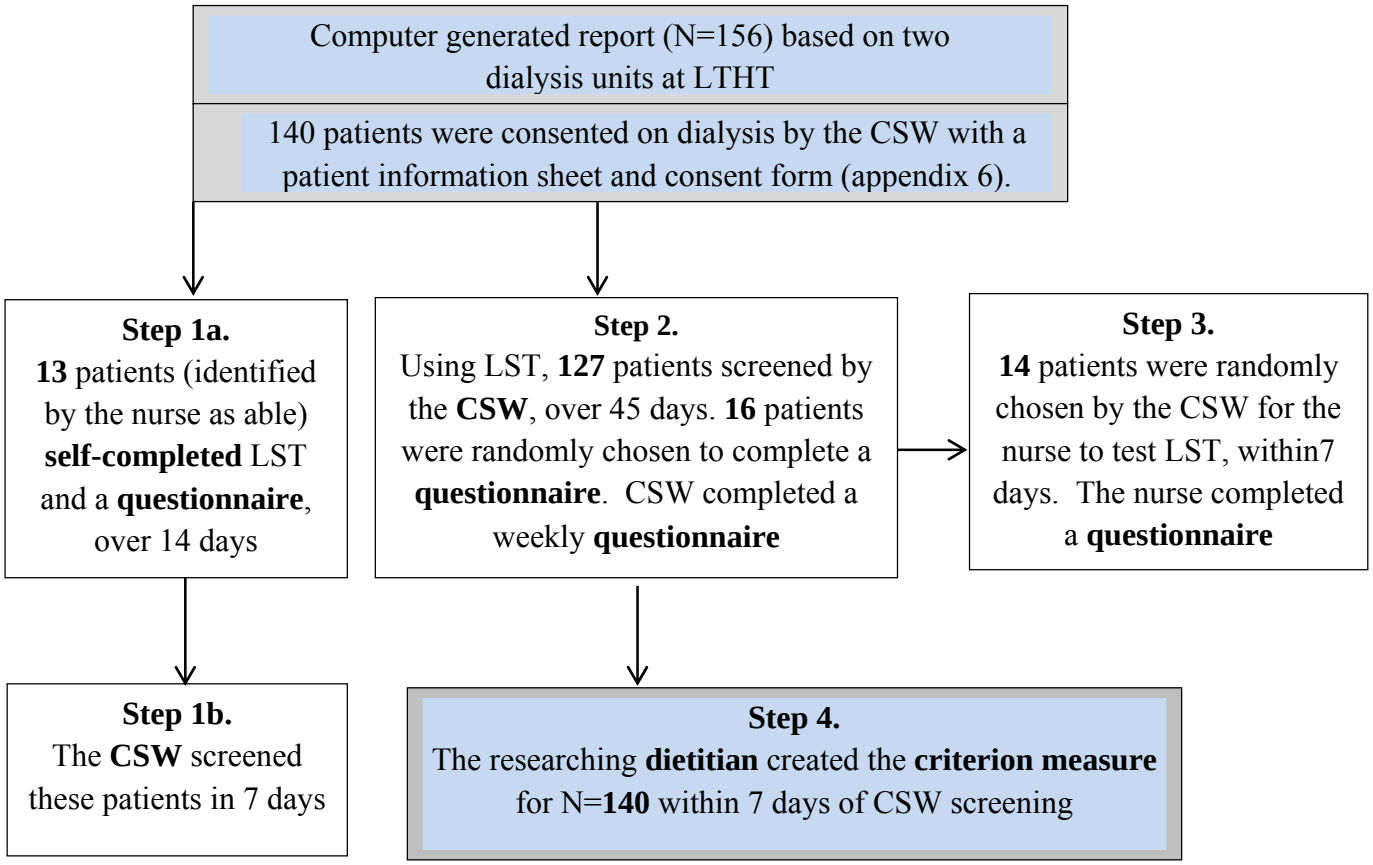


Figure 3.1. An overview of the study procedure

As outlined in Figure 3.1, with the computer report of eligible patients, the CSW co-ordinated communication with all researchers involved and researchers were kept blind to others results (as advocated by Jones, J. 2004c). The short timeframe of 7 days between methods aided fair testing conditions, by reducing the chance of alterations in malnutrition risk in a population where nutritional status is not a static entity (Weekes et al., 2004). Further methodological detail and justification is provided within Appendix 8.

A non-validated semi-structured questionnaire (in Appendix 9) was completed for NST feedback by each intended user group (recommended as part of the audit cycle by Jones, J., 2002).

The independent dietitian collated results and two weekly for ethical reasons, checked if any patients had been highlighted as at risk (a score of greater than 3), based on DCJ, to trigger a dietetic referral. Data was not compared by the researching dietitian until all data had been collected.

3.4 Data management

All data has been analysed using the Statistical Package for Social Sciences software (SPSS UK Ltd 2012, version 21). All of the data was checked for errors, missing data and outliers. During analysis the outliers were found to be patients at severe risk of malnutrition, due to their reduced frequency (n=7). These patients need to be considered in the data, so that the NST maintains sensitivity across a range of patient characteristics.

Continuous variables including characteristics such as age, time on dialysis, weight loss, weight and BMI are presented as means and as standard deviations (Burrowes et al., 2005; de Mutsert et al., 2009). None of the continuous characteristics were found to be normally distributed. Log transformations were unlikely to be of benefit due to the small sample size (Field, 2013). Non-parametric testing was therefore indicated for these characteristics, which is consistent with similar work by Campbell and Maclaughlin (2010) and Lawson, C. et al. (2012).

The majority of the variables were categorical, as ordinal data; the LST and DCJ outcome measures or as nominal data; dialysis shifts, gender, ethnicity, smoking and co-morbid conditions (consistent with Cooper et al., 2002). Categorical variables are presented as frequencies, proportions and tested with non-parametric statistics (Burrowes et al., 2005; Pallant, 2013).

3.4.1 Statistical analysis. All data was investigated by use of inferential statistics and statistical significance level was set at $p < .05$. Table 3.5 outlines the aims of analysis, attached to the hypotheses and associated statistical testing, to be performed in Section 4.

Table 3.5

Overview of statistical testing

Section	Analysis aims	Rationale	Main statistical testing
4.1	Sample characteristics compared to national results.	Assess LST transferability	Non-parametric data using Mann-Whitney (U) to test for differences (N=140)
4.2	Characteristics of those at risk and not at risk of malnutrition.	Analyse group differences	As above
4.3	Analyse the sensitivity of the LST compared with DCJ	Primary study aim (H_1)	Cross-tabulation with kappa (*k*) to test agreement with DCJ
4.3	Analyse the specificity of the LST compared with DCJ	Hypotheses (H_2)	As above
4.4	Analyse effectiveness of incomplete LSTs	Hypotheses (H_3)	As above, for LSTs that were not fully complete (n=13)
4.4	Analyse the relationship of the LST risk variables individually and in combination with DCJ	Hypotheses (H_3)	Non-parametric Spearmans Rho correlation (r) and multiple regression (β)
4.5	Analyse the reliability of the LST amongst different future users	Hypotheses (H_4)	Cross-tabulation and Kappa (*k*) to test agreement

3.4.2 Reporting of results. The data was formed as two groups in the main stem of the analysis by collapsing the four point scale, illustrated in Table 3.6, which is in keeping with the literature (Bennett et al., 2005; Campbell et al., 2013).

Table 3.6

Outcome measures as two groups

Score category	**1 to 2**	**3 to 4**
Risk category	No to Low	Mild and Moderate to Severe
Dietetic referral	**Not indicated**	**Indicated**

The ability of LST to identify two groups, firstly, those at risk and requiring dietetic referral and secondly, those not at risk that do not require a dietetic referral, is the primary outcome of this study and is paramount for future implementation. Analysis of LST accuracy over four levels is also important in indicating the effectiveness of LST across the differing risk categories.

3.4.3 Interpreting statistical testing. The Shrout Classification, Table 3.7 (cited by Jones, J, 2004b, p.308), was used to interpret cross tabulation results (Table 3.5).

Table 3.7

Shrout Classification

*K*value	Agreement
0-0.10	Virtually none
0.11-0.40	Slight
0.41-0.60	Fair
0.61-0.80	Moderate
0.81-1	Substantial

For interpreting the Spearmans Rho correlation analysis (Table 3.5) Cohen's 1988 criteria was used, as detailed in Table 3.8 (cited by Pallant, 2013, p.139).

Table 3.8

Interpretation of the correlation coefficients

r value	Correlation
0.1-0.29	Small
0.3-0.49	Medium
0.5-1	Large

3.5 Qualitative data

The nature of this study required a quantitative research model, with objectivity, although a qualitative approach was not discounted. Consideration was given to patient interviews,

however due to the sample size and patient life-stage, semi-structured questionnaires for LST feedback were more appropriate (Figure 3.1). Feedback was collated from 26/34 patients to explore discrepancies in numerical data and underlying themes, to enrich LST improvements (drawing on Jones, J, 2004a). Literature appraisal fails to show substantive research in this area of NST development, with only one author using questionnaires alongside quantitative data collection (Weekes et al. 2004).

Results

4.1 The sample population

140 patients completed the study, with 16/156 patients failing to take part (Section 3.2.4). The study sample characteristics are displayed in Table 3.3 and are compared with 2013 UK survey data (based on 71 UK centres, RA, 2013) in Table 4.1.

Table 4.1

Sample characteristics (N=140) compared with national HD data

Sample characteristics	Study population	National data (RA, 2013)
Age (Years), Median (range)	65.7 (19.3-89.6)	66.4 (not available)
Over 65 years	53%	49%
Over 75 years	26%	15.7%
Gender (Male)	62%	62%
Ethnicity White	74%	79.3%
Diabetes (%)	17% (19% missing)	35%
> 1 co-morbidity* (%)	65% (16% missing)	52.9%
Cardiovascular disease (%)	4% (17% missing)	19%
Smoker (%)	20% (30% missing)	14%
Weight (Kg) (SD)	78.6 (± 20.9)	Not collated
BMI (kg/m^2) (SD)	27.7(± 6.7)	Not collated
Weight loss (%) (SD)	1.4 (± 3.39)	Not collated

Note. *including emphysema, diabetes, malignancy and liver disease

National data is not available as raw data and so trends only are considered here, as opposed to statistical testing.

4.2 Sample characteristics as two dichotomous groups

The population can be defined as two subsets, in Table 4.2, as at risk of malnutrition (and requiring a dietetic referral) and not at risk of malnutrition (not requiring a referral), based on DCJ.

Table 4.2

Sample characteristics as two dichotomous groups

Characteristics	At risk(n= 15)	Not at risk(n= 115)
Age (years), Mean (SD)	61.92 (± 18.253)	62.4 (± -15.7)
Gender -Male (%)	52	64
Ethnicity – White (%)	72	75
Dialysis vintage, Mean(years), (SD)	5.09 (± 6.07)	3.96 (± 4.96)
Cardiovascular disease (%)	52	38
Smoker (%)	24	17
Diabetes (%)	5	62
>1 co-morbidity (%)	77	62
Post weight (Kg), Mean (SD)	66.3 (± 14.11)*	81.27 (± 21.27)
BMI (Kg/m^2), Mean (SD)	23.3 (± 23.3)*	28.6 (± 6.7)
Weight loss (%),Mean (SD)	7.2 (± 4.2)*	0.8 (± 1.7)

Note. * p<.001

The only statistical difference identified between the groups was in weight, BMI and weight loss, which is an anticipated result (p< .0001). Equally, these characteristics were the only ones that correlated with risk of malnutrition (r=.3 to.7) (p<.001) (shown in Appendix 10).

4.3 Sensitivity ($H_{1)}$ and specificity (H_2) of the LST compared with DCJ

4.3.1 Results as two dichotomous groups. Figure 4.1 shows the patient numbers identified to be at risk of malnutrition (requiring a referral) and not at risk (not requiring a referral) (N=140), for LST compared with DCJ.

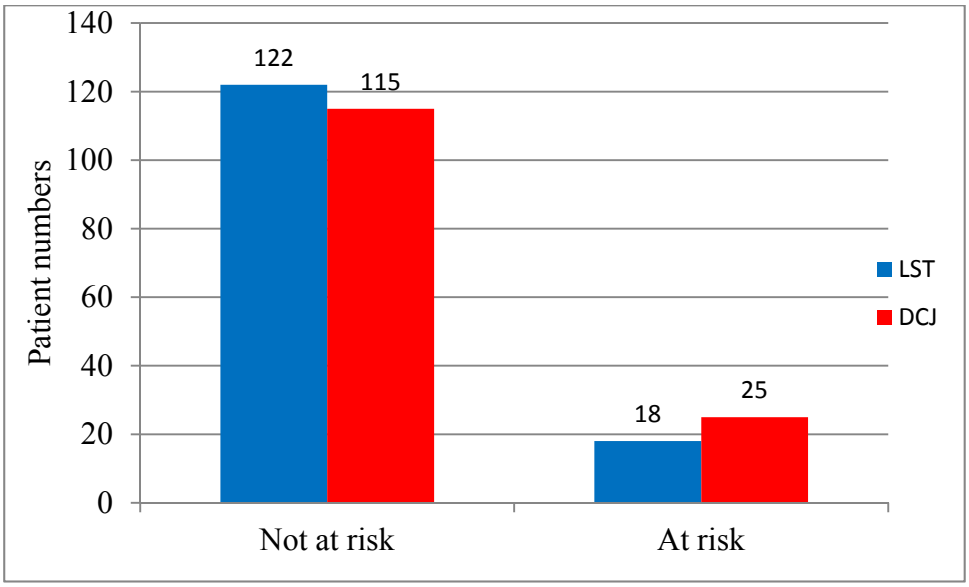


Figure 4.1. Identified malnutrition risk (N=140)

LST correctly identified 72% of patients to be at risk of malnutrition (sensitivity), as compared with DCJ. LST correctly identified 100% of patients not at risk of malnutrition (specificity). Statistically, there was substantial consistency between the results for DCJ and LST, as displayed in Figure 4.1 (k=.8) (p= .0001) (Pallant, 2013). Furthermore, the discrepancy between LST and DCJ was not deemed to be statistically significant, χ^2 (1, N=140)=2.38, p= .12.

Sensitivity and specificity was considered further in two patient subsets, as outlined in Table 4.3, to assess if methodological differences altered results.

Table 4.3

Sensitivity and specificity in patient subsets

Subset analysis	Sample number	Sensitivity (%)	Specificity (%)	Kappa
Patients with fully completed tools	127	73	100	*K*=.8 (p< .001)
Patients where DCJ based on direct contact (as opposed to records)	88	75	100	*k*=.8 (p< .001)

Accuracy of LST can be further analysed by the following calculations in Table 4.4.

Table 4.4

Further considerations for accuracy

Accuracy calculations	Results
Mis-classification rate	4%
Rate of accuracy	96%
The likelihood ratio (the likelihood that the patient will test positive for the disease)	7.4

4.3.2 Referral rates. Based on DCJ (Figure 4.1), 25/140 patients required dietetic referral, this equates to an 18% referral rate. Table 4.5 illustrates estimated quarterly referral rates indicated by DCJ, current practice (43% of DCJ) and LST (72% of DCJ) at a local and national level.

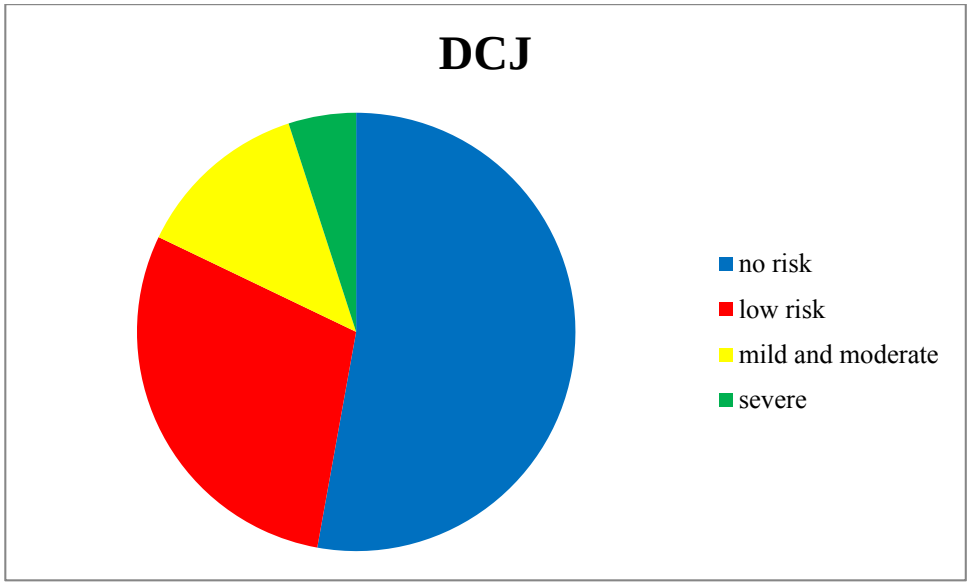
Table 4.5

Referral rates

Method for screening	Quarterly	Quarterly difference to DCJ	Annually	Annual difference to DCJ
DCJ identified	90	N/A	360	N/A
LTHT with LST	65	25	260	100
LTHT population currently	39	51	156	204
National referrals* for DCJ (using an 18% referral rate)	4208	N/A	16, 832	N/A
National referral numbers for LST (72% of DCJ)	3029	1179	12,119	4713
National referral numbers for current rates (43% of DCJ)	1809	2309	7237	9595

Note. * based on Renal Registry numbers of 23,378 (RA, 2013).

4.3.3 Audit results expanded over a scale of four. Effectiveness of LST in identifying malnutrition risk across four risk categories is illustrated in Figure 4.2.



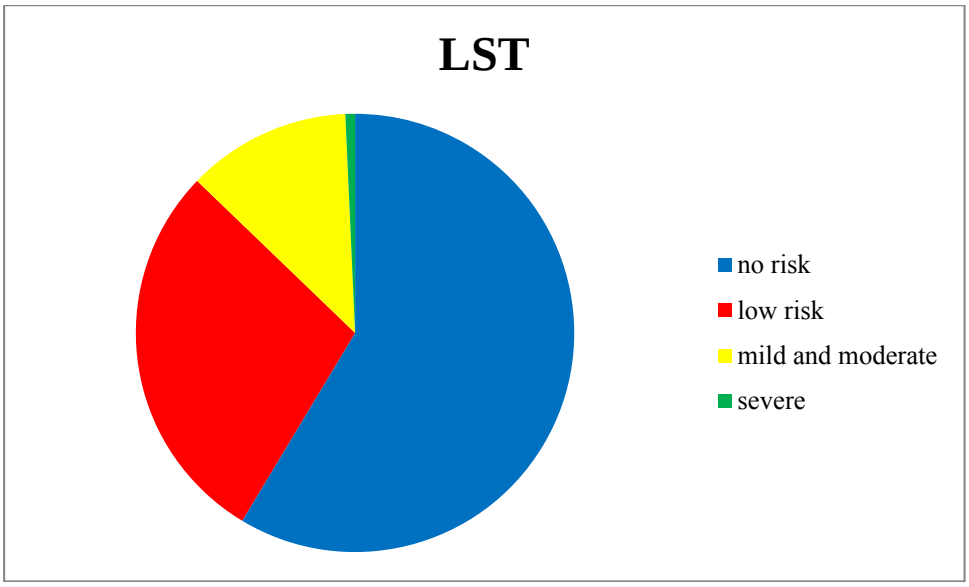


Figure 4.2 Malnutrition risk along a scale of four

There was a high association between the results for LST and DCJ across a scale of four, χ^2 (9, N=140)=120.89, p< .001. Furthermore, there was no statistical discrepancy between the results for both methods, χ^2 (3, N=140)=6.1, p= .11. On the other hand, Kappa analysis showed that there was only fair agreement (*k*=.48) (see Table 3.7). Table 4.6 and Figure 4.3, illustrates that this result suggesting limited consistency between DCJ and the LST may be attributed to the discrepancies between the no risk and severe risk groups.

Table 4.6

Accuracy of LST compared with DCJ across a four point scale LST (N=140)

Variable	Score 1 = No risk	Score 2 = Low risk	Score 3= Mild-moderate	Score 4 = Severe
Accuracy	89%	98%	94%	17%

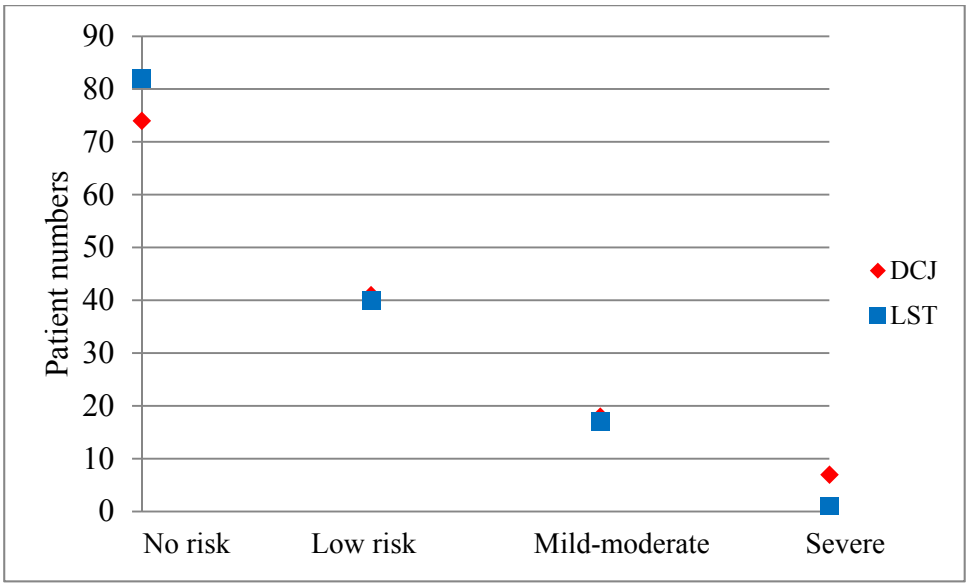


Figure 4.3. Agreement between malnutrition risk categories for DCJ and LST

There were 37 discrepancies across the results for the four point scale between DCJ and LST, seen in Figure 4.4 and all discrepancies were by 1 category only.

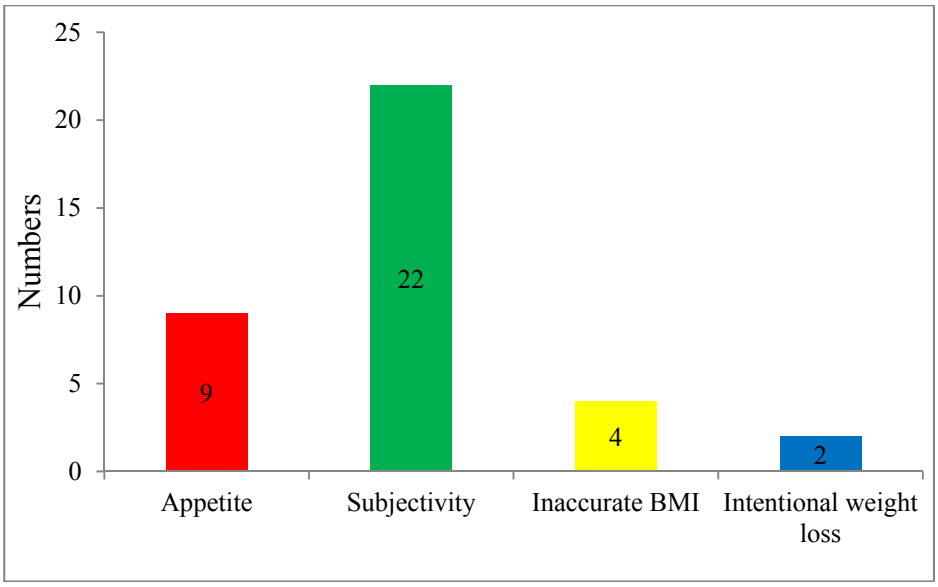


Figure 4.4. Causes of discrepancy

Despite these discrepancies, results can suggest rates of risk of malnutrition (Table 4.7).

Table 4.7

Incidence of malnutrition risk

Risk of malnutrition	Based on DCJ (%)	Based on LST (%)
Score greater than 3; Category 3+4=	13%+7%= 20%	12%+1%=13%
Score greater than 2; Category 2+3+4=	29%+13%+7%=49%	29%+12%+1%=42%

4.4 Risk variables in LST completion (H_3)

4.4.1 Analysis of partially completed tools. The comparative efficacy of tools that were not fully complete (n=13) showed a sensitivity of 67% and specificity of 100%. There was moderate agreement (*k*=.8) (Table 3.7), although this was not as significant as the LSTs that were fully completed (p= .005, see Table 4.3).

4.4.2 LST risk variables - univariate analysis. It is important to consider the usefulness of the LST objective and subjective nutritional risk variables (see Section 2.5.1). Table 4.8 shows the correlation of LST nutritional risk variables, as individual variables, compared with malnutrition risk as assessed by DCJ (in fully completed LSTs, n=127).

Table 4.8

Spearmans rho correlation analysis of LST risk variables to DCJ (n=127)

Risk variable	A- Weight change	B- DI	C- appetite	D-PA	E- BMI	F-Weight loss
Correlation co-efficient	.58*	.46*	.40*	.68*	.49*	.75*
Interpretation	Large	Medium	Medium	Large	Medium	Large
Co-efficient of determination	33%	21%	16%	46%	24%	56%

Note. *p<.001

4.4.4 LST risk variables - multivariate analysis. Table 4.9 shows regression analysis of LST nutritional risk variables, relative to each other, compared with malnutrition risk as assessed by DCJ (in fully completed LSTs, n=127).

Table 4.9

Contribution of LST risk variables

RISK VARIABLE	Standardised Beta value	Unique contribution*	P value
A-weight change	.65	1	.335
B-DI	.20	4	< .001**
C-appetite	.04	6	.445
D-PA	.16	5	.155
E-BMI	.35	3	< .001**
F-Percentage weight loss	.46	2	< .001**

Note. *1=highest ** statistically significant

Stepwise analysis showed the strongest subset of nutritional risk variables in LST for identifying risk of malnutrition, to be weight loss (F), BMI (E), DI (B) and PA (D) (Appendix 10, model 4, at R=.903). This model of risk variables explains 90% of the variance.

A scatterplot provides an illustration of the appropriateness of risk variables. Figure 4.5 displays results for BMI (Variable E) across the sample, including the HD established cut-off point of risk of malnutrition at 23kg/m^2 (Kovesdy & Kalantar-Zadeh, 2012). A further objective scatterplot for weight loss can be seen in Appendix 10.

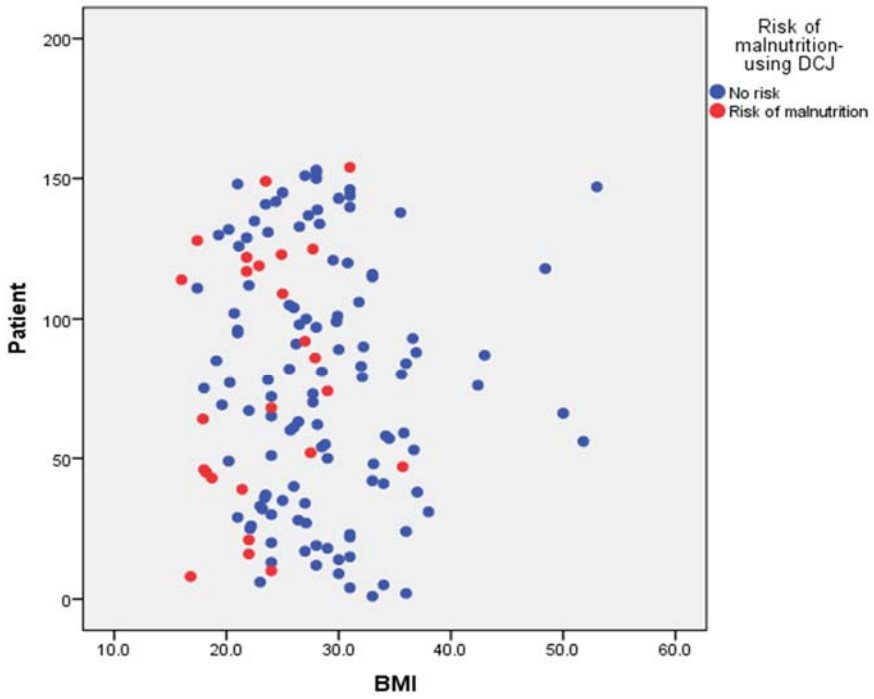


Figure 4.5. BMI of those at risk of malnutrition and not at risk of malnutrition

Figure 4.6 shows subjective questioning results for the sample for appetite (variable C) (see Appendix 10 for further scatterplots).

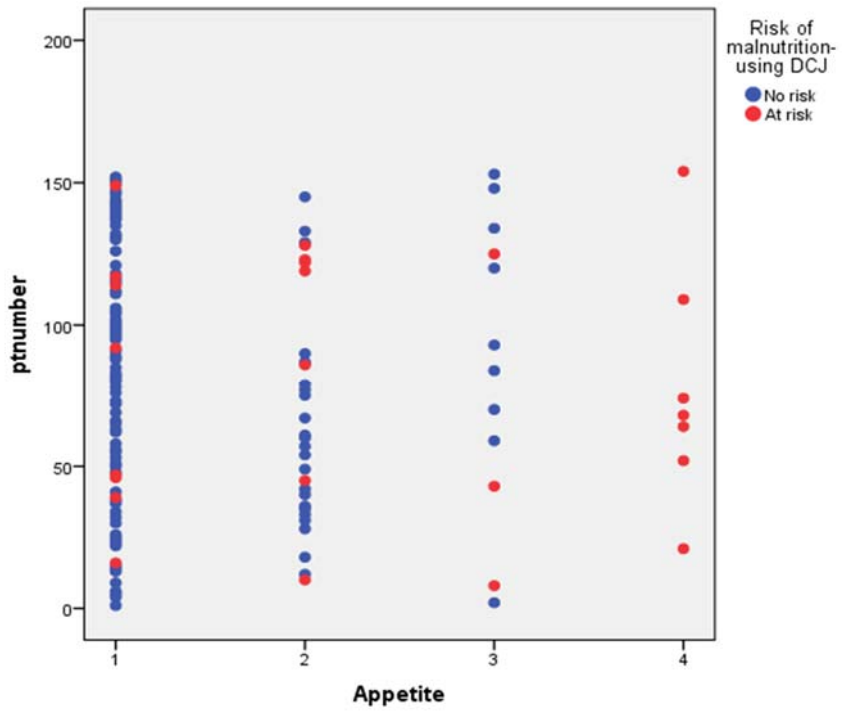


Figure 4.6 Appetite of those at risk of malnutrition and not at risk of malnutrition

4.4.5 Producing a subset. Without appetite sensitivity is 73%, specificity is 100% and there was moderate agreement, n=127, *k*=.79, p= .0001.

4.5 Analysis of the reliability of LST (H^4)

Reliability testing was based on the patient versus the CSW (see Table 4.10) and the N/S versus the CSW (Table 4.11).

Table 4.10

Reliability with the patient

	Patient versus CSW	CSW versus DCJ	Patient versus DCJ
Sensitivity	2/2 (100%)	1/2 (50%)	1/2 (50%)
Specificity	11/11 (100%)	11/11 (100%)	11/11 (100%)
Agreement	Substantial (*k*=1) (p<.001)	Moderate (*k*=.63) (p= .02)	Moderate (*k*=.63) (p= .02)

Table 4.11

Reliability with the nurse

	N/S versus CSW	CSW versus DCJ	N/S versus DCJ
Sensitivity	2/2 (100%)	1/2 (50%)	1/2 (50%)
Specificity	11/12 (92%)	12/12 (100%)	11/12 (92%)
Agreement	Moderate (k=.63) (p= .01)	Moderate (k=.63) (p= .01)	Fair (k=.42) (no significance p= .12)

3% (4/140) patients had the LST completed by a carer and these were consistent with DCJ.

4.7 Qualitative analysis

26/34 questionnaires were completed, 9 patients declined and not all questions were answered (see Table 4.12).

Table 4.12

LST feedback

Questions	Completion number	Frequency	Comments
Was the rationale for the tool clear?	26	Yes=26/26 (100%)	'Easy to understand'
Were the questions clear?	26	Yes=21/21 (100%)	'Answers don't always say it how I would say it'
Were the answers appropriate?	26	Yes=19/21 (90%)	'Answers could be more detailed' 'Intentionally losing weight'- not clear enough (n=2)
Comments on LST appearance?	24	No=15/18 (83%)	'Easy to complete' 'Easy to use'
Did LST agree with how the patient felt about malnutrition risk?	21	Yes= 17/21 (80%)	'Not at risk but concerned about weight' 'I lost weight in hospital but now am ok'
Comments on LST use in practice?	21	No=11/16 (69%)	Nil Quick and simple to use.
Further comments	4	4/21 (19%)	'makes me aware that the hospital is prepared to provide support'

Feedback was considered for future improvements, Table 4.13.

Table 4.13

Future improvements based on qualitative results

Improvements based on feedback
Review wording to focus the NST on intentional weight loss
Reiterate the importance of the distinction of DI and appetite, within user education

Consider case scenarios within training, to aid users choosing the appropriate risk category, for example regarding recent hospital admissions

Discussion

5.1 Overview of study results

The findings would appear to demonstrate that the LST is consistent with DCJ in identifying those at risk and those not at risk of malnutrition within the HD patient sample. LST reached high levels of sensitivity (H^1) and specificity (H^2) that are comparative to current NHS diagnostic tests for medical parameters (to be discussed in Section 5.4.1). A particular strength of the Leeds tool was that it maintained comparative efficacy in those that could not fully complete the questions (H_3), due to dementia, learning difficulties and language barrier. All of the LST risk variables had a relationship with risk of malnutrition, as identified by the dietitian. In the pursuit of a simplified NST, removal of appetite variable produced no change in LST performance (H_3) and therefore omission should be considered before LST implementation. Reliability testing showed that LST produced consistent results (H_4) between different intended users (patients and N/S) and in turn, they evaluated LST positively for practical acceptability.

5.2 Discussion outline

Within this chapter key study results will be evaluated alongside literature appraisal and will consider LST:

- Transferability
- Validity and content
- Reliability
- Feedback

This is in fulfilment of the study hypotheses (Section 2.7) and as a necessity of effective NST testing (Table 2.1).

5.3 Sample characteristics

Reaching the required sample size means results can be interpreted with confidence. This is with the exception of reliability analysis which involved a small sample, nonetheless it was a feature that other authors omit (as commented by Steenson et al., 2013). Equally presentation of sample size calculations, central to research, are also lacking, as summarised by Jones, J. (2002) finding only 1/44 NST papers discussed sample requirements.

The 10% (16/156) that failed to complete was comparable to similar studies by Jones, C. et al. (2004) at 20% and Bennett et al. (2012) at 16%. With only three patients declining to take part in this research, LST had a completion rate of 98% (140/143), which is in keeping with the work by Lim et al. (2012) and is of primary importance for future NST compliance. With such a low attrition rate (n=16) the sample, recruited from two different units, were thought to be representative of the LTHT HD population locally (140/500 HD patients) (See Appendix 10). This is fundamental in considering transferability of LST (Appendix2) to LTHT and further afield. Sample characteristics appeared to run in parallel for age, gender and co-morbidities with other relevant authors (Yamada et al., 2008; Kalantar-Zadeh et al., 1999) and also with national HD data (see Table 4.1). The latter conclusion may be biased by the extent of missing information within the research sample (see Table 4.1) and also due to the lack of availability of raw national data, statistical testing could not be performed. Comparisons to national characteristics are therefore based on proportions, which is consistent with Steiber et al. (2007) comparing sample characteristics to a larger US data set.

Overall, sample characteristics appear comparable to national HD statistics, especially with regards to age, gender and ethnicity (Table 4.1). Diabetes and cardiovascular disease have an observable difference (about 20%), in Table 4.1. Correlation analysis, however, failed to identify a relationship between any of these characteristics and risk of malnutrition (in Table 4.2). Only weight, BMI and weight change correlated, which was anticipated (p= .0001) (see 5.5.1, Appendix 10). A larger sample size may detect correlation of other characteristics with malnutrition, with varying reports within the literature. As space is not permitting to discuss finer detail, it would be

reasonable to conclude that there was no obvious spectrum bias and transferability of LST to other centres could be considered with statistical testing of a larger cohort.

5.4- Sensitivity (H_1) and specificity (H_2) of the LST

5.4.1 Results as two groups. Central to this audit is the evaluation of LST performance compared with the criterion measure of DCJ. The need to correctly classify all patients at risk of malnutrition and therefore requiring a dietetic referral, takes precedence to ensure that resources are directed appropriately (discussed by Ferguson et al., 1999). There is no generic level of diagnostic accuracy, as it is dependent on the test being performed and the consequences of failing to identify those at risk. NHS established sensitivity and specificity levels are set at 70% for many medical parameters, including identification of swallowing problems after a stroke, prediction of falls risk and identification of risk level of ovarian cancer (Scottish Intercollegiate Guidelines Network, 2010, p.4; NICE,2013, p.30; Royal college of gynaecology, 2003, p.3, respectively). The literature recognises this accuracy cut-off of at 70% for NSTs in the HD setting (Bennett et al., 2005, p.145).

LST achieved a high level of sensitivity (72%) and specificity (100%), particularly as it is comprised of mainly subjective variables. Statistical testing supported these conclusions (Section 4.3.1), showing moderate agreement and a large association between LST and DCJ results (p= .0001). Furthermore there was a lack of statistically significant discrepancy between both methods.

Sensitivity improved further in the subset of patients that completed all of LSTs risk variables (Table 4.3). Statistical testing continued to show moderate agreement (k=.8) and limited statistical difference between methods (p< .001).

With the accuracy rate of 96%, mis-classification rate of 4% and the observed likelihood ratio (Table 4.4) the LST appears to have functional value (Cooper et al., 2002, p.131).

MUST has demonstrated higher levels of accuracy, 93% sensitivity and 100% specificity in 400 hospital patients however this study excluded patients with ESRF (Ferguson et al., 1999). These results are not transferable to the study setting, as discussed in Section 2.4, as MUST has a heavy reliance on objective measures, which undermine its diagnostic ability in HD patients. Furthermore this sample had relatively low levels of malnutrition (16%).

SGA has shown increased sensitivity compared to the current study, with 83% sensitivity and 93% specificity, however this was based on the comparison of SGA with an expanded version of itself (PG-SGA) and was in a small sample size (Desbrow et al., 2005). Further bias was introduced by the researcher completing SGA from the PG-SGA answers. This high level of sensitivity is not consistently shown for SGA however, as described by Gurreebun, Hartley, Brown, Ward & Goodship. (2007) who reported SGA to have a sensitivity of 32% to the criterion measure which was BMI (<23kg/m^2 signified at risk), albumin or weight loss (of >5%), which in isolation are not substantiated criteria and may explain the particularly poor performance.

Even though comparable to other research, 72% sensitivity in the current study means that 28% of patients requiring referral would fail to be identified. In terms of referrals, 25 patients from the LTHT HD population would be missed by the LST compared with DCJ at any one time (Table 4.5). These patients may also be told that they were not at clinical risk of malnutrition, thus allowing malnutrition risk to progress. The advocated monitoring and repeat NS for nutritionally vulnerable patients (set at three monthly by the LTHT team, or as clinically indicated) means that HD patients that are missed are not overlooked (recommended by NICE, 2006; RA, 2010). LST also improves upon the current uncoordinated dietetic referral system which generated 39 referrals in the last quarter, equating to 43% of those identified by DCJ and therefore failing to refer 51 patients. Table 4.5 is provided for illustrative purposes, showing these figures calculated up for estimated annual referrals within LTHT and at a national level. Ultimately however, these figures are presumed to be an overestimation, as at repeat screening a

number of the cohort would already be under dietetic care and nutritional improvements may reduce the risk level observed.

Implementation of LST would not only lead to an increase in dietetic referrals, estimated at 17%, but the system would be more likely to generate appropriate referrals. Oakley and Hill (2000) report estimated referral rates, at 77%, on future implementation of an NST within a hospital ward. These results appear particularly high and may have been skewed by the fact that scoring and wording was altered part way through and retrospective data was included. These anticipated referral rates therefore require monitoring, alongside analysis of cost-effectiveness versus clinical outcome improvements, which is a key area needing research (BAPEN, 2005; NICE, 2006). The LST high level of specificity is important as it suggests that wasting finite resources would be kept to a minimum.

5.4.2 Results as a four point scale. Analysing results as two categories defeats the rationale for having multiple strata with differing dietetic actions for each category (as outlined by Campbell et al, 2007). Therefore consideration must be given to accuracy along the extended four point scale (Figure 4.2). Statistical testing shows conflicting results for LST across 4 risk levels, on the one hand there was a high association between each method across each risk level ($p < .001$) and there was a failure to identify statistical discrepancy at each point ($p = .11$). Conversely, agreement analysis showed that there was only fair consistency ($k = .48$) ($p < .001$). The latter may be explained by the results in Figure 4.3 and Table 4.6, whereby there was a good level of accuracy 89% to 98% across all levels except for those in the severely at risk group (at 1/7, 17%), thus skewing results.

60% of discrepancies were based on subjective differences between LST and DCJ (Figure 4.4), mainly due to how the patient perceived answers (consistent with Cooper et al., 2002). For example, patients perceived their DI to be better than that assessed by the dietitian (described by Cupisti et al., 2010). Despite these discrepancies, overall LST had high levels of accuracy, especially in the early stages of malnutrition risk, where there is proportionately a larger number.

Bryan et al. (1998) explain that subjectivity of staff is more accurate in patients with chronic conditions, due to the frequency at which the patients are seen. De Mutsert et al. (2009) advocate training as an integral part of NS, to enrich understanding of the nutritional parameters in ESRF.

Accuracy results do however suggest that further work is required in testing LST in a larger sample, particularly in those at severe risk. The low rates of severe risk are comparable to similar studies, see Table 5.1, even in a larger sample (de Mutsert et al., 2009) (n=1601).

Table 5.1

Literature based incidence rates of risk of malnutrition

Study	Assessment method	Sample size N=	No risk (%)	Low risk (%)	Mild to moderate Risk (%)	Low to moderate combined (%)	Severe risk (%)
This study	DCJ by dietitian	140	53	29	13	42	7
This study	LST by CSW	140	58	29	12	41	1
Cooper et al. (2002)	SGA by dietitian	76, 52 HD patients	58			34	8
Visser et al. (1999)	SGA as a mean of 2 N/S	22, 13 HD patients	64			27	9
De Mutsert et al. (2009)	SGA by >76 N/S in 38 centres	1601	72			13	5

There was a 20% incidence of risk of malnutrition within LTHT, based on DCJ and this compared with 13% by LST, determined by the referral cut-off point decided by LTHT dietitians (Table 4.7). Nutritional studies often incorporate low to severe risk (Table 5.1) and so with this guidance the incidence rate at LTHT increases to 49% based on DCJ and 42% by LST. These levels are comparable to literature established rates. Cooper et al. (2002) and Visser et al. (1999) report a proportionately lower risk than the current study, this may be attributed to their inclusion

of HD and peritoneal dialysis patients, with the latter dialysis group being less nutritionally deplete on dialysis treatment over time (Jager et al., 2001). De Mutsert et al. (2009) also report a lower incidence of risk and this may be as a result of it being a comparatively large study, based in the Netherlands and with baseline differences in ethnicity (92% white) as compared with the UK HD and study population (in Table 4.1). The authors deduced dietetic intervention before patients reach ESRF contributed to low rates. Consequently, this highlights NS as a priority in the early stages of ESRF and that a prompt dietetic referral should be triggered earlier, in those at low risk (a score of two as opposed to three).

5.4.3 Summary. Sensitivity and specificity results support H_1 and H_2 and oppose H_0

5.5 Risk variables in LST completion (H^3)

Nine percent (13/140) of HD patients were unable to converse, due to dementia, learning difficulties and language barriers. Despite the subjective risk variables not being completed (A to D) the sensitivity and specificity of LST remained at a modest level (67% and 100% respectively) ($p= .005$). This analysis should be considered with caution as numbers were small and only three were at risk (See 4.4.1). As this is a minority HD section, calculations estimate that eight patients would be at risk, based on DCJ and three patients would fail to be referred by LST. Representing this patient group is a distinct feature of this study, with many other studies simply excluding them (as seen in Yamada et al., 2008). One study gave those unable to answer an immediate referral and thus may be wasting resources (Ferguson et al., 1999). Although LST is not equally as effective as fully completed tools, supporting H_3 and opposing H_0, it provides a starting point for future work and through the process of NS these patients would be monitored at regular intervals.

5.5.1 LST risk variables. Considering the appropriateness of risk variables contained within LST (Appendix 2) is an important aspect, due to the lack of defined nutritional parameters for NST inclusion in the HD setting. The results in table 4.8 show that all of the nutritional risk variables within LST individually correlated with risk of malnutrition as determined by DCJ. All of the results were highly statistically significant ($p<.001$). Both objective and subjective risk

variables provided an important contribution in the identification of malnutrition risk (an average of 40% and 29%, based on Table 4.8).

Both correlation (Table 4.8) and multiple regression (Table 4.9) analysis highlighted weight loss, BMI, DI and PA most favourably (see Appendix 10, model 4, SE=±0.4). In conjunction these four risk variables had a 90% overlap with DCJ (P<.001), which is comparatively better performance than the literature. Enia et al. (1993) for example, found that the nutritional measures within their study correlated to 56% of risk of malnutrition, as determined by SGA.

In the present study the objective measures BMI and weight loss (variable E & F) correlated the most with risk of malnutrition, Table 4.8 - 4.9. This is an anticipated result, as the at risk group showed a statistical difference in weight (by 15kg), BMI (by 5.3kg/m^2) and weight loss (by 6.4kg, p= .0001). Bennett et al. (2012) supported this conclusion, finding a 10.8 kg reduction of weight in the at risk group (p= .04). Equally, Cooper et al. (2002) reported a statistically significant 3.2kg/m^2 reduction in BMI in those at risk (p .0001).

Results show that weight loss and BMI, do however require DI and PA in combination to produce the most effective version of LST. Furthermore, based on clinical observation LTHT and UK renal units vary in their quality of fluid management based on staffing, expertise and equipment availability and therefore the accuracy in estimating flesh weight and in turn percentage weight loss and BMI is presumed to be variable due to the complexities involved. The inappropriate or lack of adjustment for fluid weight may explain why some authors struggle to identify statistical difference with BMI , as seen in the study by Lawson, C. et al. (2012) when using MUST in a renal population. Equally, Enia et al. (1993) found limited correlation with weight loss and risk of malnutrition, there was observed fluid retention in those at risk and thus the fluid may have masked any flesh weight loss. Electronic aids may improve NST sensitivity and speed up NST completion (Elia & Stratton, 2011), but this is reliant on appropriate weight adjustments being inputted.

There are further limitations with BMI as a sole diagnostic measure (Janardhan et al., 2011) as its cut-offs may vary; in patients from Asian heritage, the older adult, patients with amputations and muscular patients (Kovesdy & Kalantar-Zadeh, 2012). Therefore using BMI in an NST for a population with mixed patient groups may mean sensitivity of the NST fluctuates. Figure 4.5 illustrates that any BMI can be at risk of malnutrition and not just below a specific value recognised as 23kg/m^2 in the literature (Kovesdy & Kalantar-Zadeh, 2012).

Despite the limitations of the objective measures, 80% of patients with a BMI of less than 23kg/m^2 and a weight loss of >5% fell into the at risk group, therefore demonstrating the importance of their inclusion. Subjective measures of patient perceived weight change adds another perspective on weight and within this study provided the highest unique contribution to identifying risk of malnutrition (Table 4.9). Ferguson et al. (1999) do however warn that patients are commonly unsure of the extent of weight change and ultimately, it is the evaluation of both objective and subjective weight variables that improved LST accuracy.

PA appeared to highly correlate with predicting the risk of malnutrition (r=.68) (p< .001) (Table 3.8). Due to the subjectivity associated with defining nutritional related changes in PA, some authors alter the question, despite providing workshops for NST guidance (de Mutsert et al., 2009). It is interesting to note that there was no statistically significant correlation between BMI and PA within the current study, suggesting that the CSW was able to appropriately distinguish signs of wasting without relying on BMI to assess PA. This may suggest that the guidance provided at the outset of the study aided subjectivity within PA.

DI had a moderate correlation with risk of malnutrition (r=.4) (P<.001) (Table 3.8), which is consistent with Cupisti et al. (2010), although their conclusions were limited with only three patients at risk. Furthermore, the current study showed that poor DI moderately correlated with the long-term marker of nutritional status, BMI (p= .04) (consistent with Jones, C. et al., 2004).

Appetite provided contrasting results to DI, which echoes the distinction made by Kalantar-Zadeh et al. (2004) that these variables are separate entities. Appetite was consistently

the weakest variable, contributing 16% to risk of malnutrition. Kalanatar-Zadeh et al. (2004) explained that 20% (66/331) of HD patients had a variable appetite across one week and so these observed fluctuations in appetite, as opposed to prolonged symptoms, may explain why there is a reduced link with malnutrition risk. Figure 4.6 illustrates that appetite does not follow a trend and in keeping with this, results showed a failure to detect a correlation with BMI in the longer term due to its transitory nature. Burrowes et al. (2005) also reported that a poor appetite did not associate with a reduced BMI ($p = .11$), although this study only considered appetite over the previous week.

Along with being the statistically weakest variable, appetite contributed to 24% (9/37) of the discrepancies (Figure 4.4). Removal of the appetite variable from LST, in the pursuit of a simpler tool, had no significant effect on sensitivity and specificity ($p = .0001$).

5.5.2 Summary. LST is not as effective when it is not fully completed, supporting H_3 and opposing H_0. That being said, not completing or in fact removing the appetite risk variable had no effect on LST effectiveness.

5.6 Reliability of LST (H_4).

There was a high level of consistency in measurements between the CSW, the patient and the nurse (Table 4.10-4.11). However due to the low numbers used in reliability testing, with only two patients at risk, further investigation is needed to assess efficacy in user groups. Equally results are limited for carer completed LSTs, due to the numbers involved and as all patients fell within the not at risk category.

Despite reliability testing being completed in a small sample, the study made efforts to consider the perspectives of differing user groups, unlike many authors (concluded by Jones, J. 2002). Ferguson et al. (1999) provide a biased example of reliability, as although they found a substantial agreement between a nutrition assistant and a dietitian in 32 patients the NST only encompassed three questions and the researchers were not reflective of intended users.

5.6.1 Summary. It would appear that LST is reproducible between future users, supporting H_4 and opposing H_0.

5.7 LST feedback

The LST evaluated to be clear in its meaning, appropriate, easy to complete and practical, based on the user feedback (Table 4.12). As a fundamental component of NST testing, feedback is something that only a few other researchers have achieved (including Weekes et al., 2004).

Improvements based on feedback, in Table 4.13, mainly extended to training.

5.8 Improvements

There are five main areas for study improvement;

- First, the method of DCJ should be based on face to face contact within the required sample size, as opposed to a combination of direct contact or evaluation of records. The varied technique of obtaining DCJ in this study may have diluted results, as patients that had direct contact had an increased sensitivity (to 75%, $p<.001$).
- Second, DCJ and reliability testing should have been completed over a shorter time frame, within hours of LST. Varying lengths of time between methods not only provides inconsistencies in method but may also minimise the accuracy of the NST in a population where symptoms and appetite fluctuate.
- Third, data collection needs to continue for increased precision, so that an increased number of patients at risk of malnutrition can be analysed (see Appendix 7). Further reliability studies are also required.
- Fourth, increased staff guidance on interpreting patient answers may reduce respondent bias and improve LST accuracy. For example, patients may tell the health professional what they think they want to hear or the patient may unknowingly underappreciate or overestimate the answers. Training, similar to that required for MUST, is fundamental in a tool that is based on subjective questions.

- Finally, to run parallel with the quantitative data collection, a qualitative approach drawing on focus groups or case-studies may provide other perspectives.

5.9 Implications

The current study provides value and originality of an NST that has been designed and tested in a representative HD population, with the particular feature of involving intended future user groups. LST would appear to demonstrate that it is comparable to other NHS diagnostic tests and indicates that it could efficiently facilitate the targeting of resources to those in need. This research raises awareness of the nutritional vulnerability of the HD population and of NS as a long term NHS cost-saving in a climate of increased pressure on resources. Implementation at LTHT will be considered on dissemination of results to the dietetic and renal team. This work provides a platform for future studies and is to be considered as part of multicentre research by the national Renal Nutrition Group. The work will also be shared with the BDA and British Renal Symposium.

5.10 Future

The current study calls for accepted gold standard diagnostic and assessment criteria for risk of malnutrition in the HD setting. A recognised method would aid dietetic assessment, study comparisons and national and international data collation.

Monitoring the value of an NST implementation is a fundamental consideration for future research. This would encompass cost-benefit analysis of nutritional, clinical and economic outcomes associated with each risk category (as discussed by NICE, 2006). Further auditing cycles would be required on implementation to consider intervals of NS and the excluded dialysis patient groups; paediatrics, home HD and peritoneal dialysis, that are without an NST.

Conclusion

- With the rates of risk of malnutrition established at 49% within the LTHT HD population, the relevance and usefulness of LST for identifying those that require dietetic intervention cannot be disputed.
- In answer to the question, the Leeds tool demonstrated that it could identify those patients at risk of malnutrition, that it was consistent with the dietitian and comparable to other NHS diagnostic tests. In turn, resources would be directed appropriately and timely.
- The LST also provided functional value within the subsection of patients that were unable to fully complete the NST questions.
- Implementation of an NST programme advocates NS at regular intervals and so those, about a third, that the LST did not correctly identify to be at risk, would be monitored regularly.
- At the centre of LST performance was a combination of objective and subjective nutritional risk variables. These variables were valid and comprehensive in the HD setting, which has proven to be a challenging find for many researchers.
- In the pursuit of a simpler NST, the appetite variable could be removed, without reducing effectiveness.
- The tool's dependence on subjective variables does mean that effectiveness will vary depending on the user and therefore a basic education session is fundamental in enhancing accuracy.
- The LST did appear to be consistent with future users and feedback demonstrated LST to be acceptable, quick, easy and understandable. The extent and quality of the feedback gained within the study was disappointing and should be addressed in further work.

- Despite the need for future methodological improvements, the current research endeavoured to fulfil the requirements of effective NST development and testing. As a result of the varying quality of nutritional studies within the literature, this research provides improvement on studies within the HD setting.
- This study therefore provides a robust NST for a sensitive patient environment and a framework for future research within a larger regional cohort.
- Ultimately, this study raises awareness of the nutritionally fragile HD population and it also contributes to work that has been identified as a priority nationally and internationally. The results will be disseminated to LTHT renal team and considered for implementation.
- Further research would be required to determine transferability of the Leeds tool and to consider the effect of NST implementation on clinical and cost outcomes, with the overarching goal of reducing prevalence of malnutrition

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Appendix

Appendix 1. Executive summary of the previous LST audits.

Audit/tool number	Tool development	Haemodialysis sample	Reference method	Additional testing
Audit 1 Version1	Initially created based on the literature, screening tools in circulation and clinical experience.	Known to be at risk, on dietetic books N = 14	Both dietetic clinical judgement and SGA	Nil
Audit 2 Version 2	Version 2 modified on audit 1 results; -Altered BMI cut-offs -Improve wording -Remove functional ability, dialysis years, co-morbidities and GI symptoms - Add question for appetite	Random N = 14	Both dietetic clinical judgement and SGA	Small scale nursing and patient involvement in tool completion, including their feedback
Audit 3 Version 3	Version 3, modified on audit 2 results; -Remove biochemistry -Improve wording -Training as a precursor for tool use	Nil	Nil	Renal dietetic colleague semi-structured questionnaire feedback
Audit 4 Version 4	Version 4, modified on audit 3 recommendations; - Consent and introduction -Improve wording - Change scale	Nil	Nil	LTHT Patient Information Group review
Audit 5 = Masters study	Version 5, tested in the current study based on a tool modified on audit 4 recommendations; -Move BMI -Identify staff completion sections			

Audit 1 to 4	Overview
Overall response rate	99% (1/28 patients declined)
Incidence of malnutrition risk	43% (as per random sampling in audit 2)
Reference standard	SGA showed poor agreement with dietetic clinical judgement (in only 31%), compared to LST version 1 (at 68%). SGA was also 2 risk categories apart from the reference standard in 15% of cases in audit 1. In audit 2 25% of SGA referrals were inappropriate. SGA was also discredited by the feedback that wording was complicated and 'jargony' and the tool was more time consuming.
Barriers	28% of the sample could not converse to provide answers. Only 12% were able to self-complete the tool.

A full report is available on request.

Appendix 1. Continued. Justification of changes made during the LST audits.

The tool	**Introduction**	Consent options need to be included, alongside an introduction (as version 4).
	Language-	72% renal dietitians felt that the language should be more patient friendly for version 5. For example, patients often did not know their weight loss in numerical terms, considering clothing size, body size, body shape changes and using signs and symptoms may be simpler. Using portions, specific timeframes and objective measures may be easier for the patient to decipher the appropriate risk category (altered for weight change, appetite and dietary intake questions).
	Scales-	100% dietitians felt the tool should be simplified by using a scale of 1 to 4 rather than 1 to 5 (actioned from version 5). Audits showed that averaging scores worked well, particularly when not all questions could be completed. Equal weighting for each risk variable appeared to be appropriate.
	Format-	The tool, layout and font was well received by nursing staff and patients in audit 3. Feedback was positive; 'User friendly and easy to get to grips with.'
Practicality	**Considerations**	As patients are all routinely seen twice by the dietitian within the first 3 months of dialysis, it was agreed in audit 3 that the patients will only be screened after the first 3 months, 3 monthly thereof. Computer calculated objective data would be beneficial. As per audit 4 feedback, a training package is required before implementation, to equip the tool user with the appropriate interpretation skills.
Inclusion criteria	**Intake & appetite**	Fluctuations in appetite and intake appear to be common and therefore are an important variable to include.67% patients scored appetite and dietary intake differently in audit 2, suggesting the patients identify these as different entities.
	Weight	Altered BMI cut-offs improved appropriate scoring in audit 2. A couple of patients commented that they were unsure 'what BMI meant,' therefore the objective questions have been shaded and moved to the bottom, which the staff can complete (this was also highlighted in audit 4). The dietitians agreed that Target weight is the most reliable weight to use. Calculating percentage weight loss by the user, plus the patient commenting on weight change, as 2 questions (as in version 5) add strength and improve problems found with patients underestimating weight loss due to fluid bias.
	Physical appearance	A question on physical appearance was 100% useful in reinforcing appropriate scores in audit 2. It also helped in 75% who could not be conversed with.
Exclusion criteria	**Functional ability**	Appeared as a challenging question, due to difficulty associated with pinpointing the contribution of nutritional deficit in decline. Removal of this question improved scoring by 91%. Interestingly only 30% of those known to be malnourished in audit 1 felt that they had a reduction in functional capacity.
	HD vintage & comorbidities	Audit 1 & 2 showed that dialysis vintage and co-morbidities affected the results inappropriately in 100%. 60% patients were unable to detail answers.
	GI symptoms	In 65% this question affected scoring inappropriately, as although symptoms were frequently experienced they did not necessarily affect intake.
	Biochemistry	None of the biochemical parameters closely mirrored the expected relationship seen with advancing risk of malnutrition.

Appendix 2. LTHT Nutritional Screening Tool (LST)

Patient number……**NHS Number**……

Patients on dialysis can experience problems with their appetite and eating. By completing the following questions every 3 months it will highlight if you are at risk of malnutrition, so that the dietitian can help to support you with this. The questions can be completed by a clinical support worker or a nurse with you, or you can complete the questions on your own.
If you do not know the answers to the following questions please leave the questions blank.

CONSENT……...Y/N DATE ……. COMPLETED BY (name and position)……..

Circle the relevant number for A to E below. **If you do not know the answers to the following questions please leave the questions blank.**			
A. Patient reported weight change - *Have you noticed any unintentional flesh weight loss over the last 6 months?*			
1	**2**	**3**	**4**
No recent change in flesh weight	**2-4lbs/1-2kgs** and no previous history of significant flesh weight loss **or** longstanding habit of flesh weight going 'up and down'	**Over ½ stone/ 3kg** weight loss over the last 3-6 months, may be due to recent period/s of being unwell **or** a drop in a clothes size	Large weight loss of **more than a 1stone/ 6kg**, over the last 3-6 months, may be due to a long period of being unwell **or** more than 1 drop in clothes size
B. Dietary Intake-*Has your noticed any changes in your eating recently?*			
1	**2**	**3**	**4**
Eating well, 'I think I am eating enough'	**Less** than usual for **less than 2 weeks** but now i**mproving** **or** 'I have never been a big eater, but I don't miss meals'	'I am eating **50% of my meals in the last week or more'** **or** 'No change but I don't think I eat enough and I do miss meals some days'	Eating is **very poor for more than a few days** **or** 'I can't face eating a lot of the time'
C. Appetite- *How would you describe your appetite at the moment?*			
1	**2**	**3**	**4**
'No change, good appetite'	'up and down, but I always make myself eat'	' It varies, sometimes I do struggle with my appetite and my eating can suffer'	'Poor appetite most of the time,' 'not interested in food a lot of the time'
D. Physical Appearance-*Do you feel your body shape or size has changed recently? Answer the question jointly with the patient.*			
1	**2**	**3**	**4**
No change, appears well nourished	Slim but 'always been this way'	Some signs of reduced fat and muscle stores	Obvious signs of fat and muscle wasting
E. BMI- *to be completed by a staff member and is calculated by BHLY.*			
1	**2**	**3**	**4**
Greater than 25	24.9 to 20.1	20.0 to 18.6	Less than 18.5
F. Percentage weight loss - *over 3 months,* *to be completed by a staff member and is calculated by BHLY*			
1	**2**	**3**	**4**
weight gain or less than 2.0%	2.1-4.9%	5.0-9.9%	Greater than 10.0%

After answering the above questions an '*average score*' is needed

It maybe that some of the questions were unknown or unavailable. For example you may find it difficult to grade physical appearance in question E. Especially for those patients that are very slim, as they may have been slim for many years and are not malnourished. Equally in those that are very overweight, wasting maybe be hidden. Therefore it is important to ask the patient how they feel about their appearance.

To create an average score, the scores circled need to be added together and divided by the number of questions answered.

EXAMPLE- If a patient does not speak English, it may be that only **D, E & F** can be answered.

In this case scores **2+3+4 = 9 as a total score**. **9 (total score) divided by 3 (questions)** provides the **average score of 3**.

Once an 'average score' is calculated, the following screening care plan should be commenced…….

Screening care plan

Score 1-2 = No risk or low risk of malnutrition

No dietetic intervention required. Repeat Screening tool in 3 months. Consider if there is a highlighted need for a BCM

Score 3 = Mild and moderate risk of malnutrition

Inform patient of the results and gain consent before completing a dietetic referral. Consider if a repeat BCM is required.

The patient will be seen within 2 weeks

Score 4 = Severe risk of malnutrition

Inform patient of the results and gain consent before completing a dietetic referral. Consider if a repeat BCM is required.

The patient will be seen within 1 week

This action should agree with your clinical judgement

Date	Average score	Screening care plan	Action required ✓or X	Action complete ✓or X	Signature & position
		1.Repeat screening only 2.BCM 3.Dietetic referral			

Please see the dietetic referral form for other dietary referrals; Including….

- Renal dietary advice and support (for potassium, phosphate, salt, fluid)
- Therapeutic dietary advice; coeliac disease, diabetes
- Weight management advice, for example for transplant

Appendix 3a. Malnutrition Universal Screening tool (permission gained, see Appendix 5)
Retrieved from http://www.bapen.org.uk/pdfs/must/must_full.pdf

Appendix 3b. Subjective Global Assessment tool

(Taken from Steiber et al., 2004, p. 195, permission gained, see Appendix 5)

Appendix 4. Dietetic Clinical Judgement Standard

Consider each of the following criteria (1-7) to identify risk of malnutrition, scoring is based on the…….

The risk category continuum

Score	1	2	3	4
Risk	No	Low	Mild and moderate	Severe

Consider the criteria below, to provide risk category score, which will serve as the dietetic clinical judgement criterion measure.

Criteria 1	**Anthropometric Data**
MUAC/TSF/HGS Physical appearance	**Comments**

Criteria 2	**Weight**
BMI Weight History Unintentional weight loss Look at target weight, bioelectrical impedance	**Comments**

Criteria 3	**Dietary Assessment**
Using last assessment Appetite Intake Requirements Deficit Dietary restrictions Time on dialysis Problems with eating Symptoms	**Comments**

Criteria 4	**Nutrition support**
Recent nutritional support need Food fortification Nutritional supplements IDPN	**Comments**

Criteria 5	Social/ Mental Conditions affecting Intake
• Mood, confused • Neglect • Depressed • Stress • Lives alone • Reduced social contact • dementia • Quality of life • Social constraints • Age and ability with food	**Comments**

Criteria 6	Medical Conditions affecting nutritional status
• Medical Conditions Affecting Polypharmacy Medical letters Recent admissions Treatment plans Pain Dialysis	**Comments**

SGA score **7 = no risk** **6 = low** **3,4,5 = mild and moderate** **1-2 = severe**	

Comments

Overall risk category =

Appendix 5. Permission

Permission for figures used.

Permission for figure 2.1

From: kim bowra
Sent: Monday, August 18, 2014 6:16 AM
To: Franch, Harold A
Subject: Request

-Hello
I am wondering whether I could have your permission to copy the diagram of the etiology of PEW (p78) from your paper Etiology of the Protein Energy Wasting Syndrome....'in my masters work (unpublished) regarding development of a nutritional screening tool in the HD population.
Many thanks
Kim Bowra

-Franch, Harold A 18/08/2014
To: kim bowra
Yes, You may use the figure as long as the work remains unpublished. If published, you will need to go through Elsevier.
Good luck

Permission corresponding to MUST tool (Appendix 3a)
To: bapen@bapen.org.uk
Subject: MUST-permission
Hello
I am a renal dietitian in Leeds and I am currently completing my Masters
I would like to reference a copy of the MUST tool in my Appendix, which I can copy from your website
Is that ok? It will not appear in a published paper
Thankyou
Kim Bowra

Hi Kim
I can confirm that this is fine.
Kind regards
Correen (BAPEN Office)

Permission for SGA (appendix 3b)

-Using researchgate (https://www.researchgate.net/messages/179840699)

-I am currently completing my Masters and I would like to use the KDOQI model of SGA from your paper 'subjective global assessment in chronic kidney disease; a review' in my appendix.
Would that be ok?
Many thanks
Kim Bowra
Renal dietitian

-Sure that is great.
Best wishes
Alison

Appendix 5. Continued. Permission.

NHS Research and Development letter (received by email)

The Leeds Teaching Hospitals NHS
NHS Trust

Kim Bowra
Renal Dietitian
Leeds Teaching Hospitals NHS Trust

Research & Innovation Directorate

34 Hyde Terrace
Leeds
LS2 9LN
Tel: 0113 392 2878
Fax: 0113 392 6397

www.leedsth.nhs.uk/sites/research_and_development

17th January 2014

Dear Ms Bowra,

An audit to test if the LTHT nutritional screening tool can identify haemodialysis patients at risk of malnutrition.

Thank you for asking me to review the above study.

After reviewing your project, it is my opinion that it falls into the NHS category of "Service Evaluation/Development", rather than "Research". As such, it does not require NHS Research Ethics or R&D approval. ***It will require managerial approval within the Trust Directorate/Clinical Service Unit where the study takes place.***

It is, of course, important to ensure that you meet all the requirements for patient confidentiality, data protection and information governance. The best way to do this is to pseudoanonymise the data you collect and analyse. It would also be good practice to seek written informed consent from the patients who take part.

Yours sincerely,

Dr Derek R Norfolk
Associate R&D Director

Appendix 5. Continued. Permission.

Consultant Clinical Service Unit approval (received by email)

Department of Renal Medicine

St James's University Hospital
Beckett Street
Leeds
LS9 7TF

Tel: (0113) 243 3144
www.leedsth.nhs.uk
Direct Tel: (0113) 206 4534
Direct Fax: (0113) 206 4111

TO WHOM IT MAY CONCERN

Date Dictated: 21 Jan 2014
Date Typed: 21 January 2014
Our Ref: EJD/SH

Dear TO WHOM IT MAY CONCERN

Dietetic Audit - Nutritional Screening - An Audit to Test if Nutritional Screening Tool Can Identify Haemodialysis Patients at Risk of Malnutrition

This letter is to confirm that we are happy for Kim Bowra, Renal Dietician, to undertake the above audit of haemodialysis patients receiving treatment in the Leeds Teaching Hospitals NHS Trust.

Yours sincerely

Electronically signed by
Dr Emma Dunn
Consultant Nephrologist

Appendix 5.Continued. Permission.

Nursing Clinical Service Unit approval

The Leeds Teaching Hospitals NHS
NHS Trust

To Whom it May Concern

Direct line: 0113 2064947

Email: Beverley.craggs@leedsth.nhs.uk

28 January 2014

Dear Sir/Madam

An audit to test if the LTHT nutritional screening tool can identify haemodialysis patients at risk of malnutrition.

Kim Bowra - Renal Dietician

I write to confirm that I give permission for a Clinical Support Worker working 30 hours per week for the above Project and that nursing involvement will be based around working practice.

If you need any further information, please do not hesitate to contact me.

Yours sincerely

Beverley Craggs
Matron - Hepatorenal Services

Appendix 5. Continued. Permission

University of Chester FREC approval

University of Chester

Faculty of Life Sciences
Research Ethics Committee

frec@chester.ac.uk

Kim Bowra
Headingley
Leeds

11th August 2014

Dear Kim,

Study title: **An audit to test if the LTHT nutritional screening tool can identify haemodialysis patients at risk of malnutrition.**
FREC reference:887/14/KB/CSN
Version number: **2**

Thank you for providing the documentation for the amendments recommended following the approval of the above application. These amendments have been approved by the Faculty Research Ethics Committee.

- Participant Information Sheet, version 3 and attached Participant Consent Form
- Data Collection Sheet, version 3

With the Committee's best wishes for the success of this project.

Yours sincerely,

cs Committee

Appendix 5. Continued. Permission.

Funding letter-LTHT Charitable foundation

The Leeds Teaching Hospitals NHS
NHS Trust

Tel Enquiries: Tara Bain (0113) 206 7358
E-Mail: tara.bain@leedsth.nhs.uk
Ref: BM/TB/LW
Date:08 August 2013

Dear Kim
Chief Nurse Education Fund - Charitable Foundation

Thank you for your application to support the '*Masters Qualification in Nutrition and Dietetics'' Course* that you wish to undertake.

I am pleased to inform you that the Charitable Foundation will provide 75% (£1237.50) for the current academic year (2013/ 14) in support of your application. The remaining 25% of the fees should be met by yourself.

In order to access these funds, you will need to forward me an original invoice from the attending University. This invoice should be forwarded to Tara Bain, Nursing Directorate, at the above address. Once this invoice is received a cheque will be raised and sent directly to the attending university along with the original invoice. Alternatively you can pay for this course yourself and then forward your invoice with receipt to Tara Bain at the above address, we will then reimburse you by raising a cheque in your name and sending it to your home address (please ensure you notify me of this). It will be your responsibility to pay the invoice in full. Will you please liaise with your Course Provider to ensure you are able to produce the invoice no later than September.

Please note that the funding is for course fees only. Reimbursement for travel expenses, accommodation and books, if appropriate, will be subject to negotiation with your manager.

If you have any queries, please do not hesitate to contact me.
May I take this opportunity to wish you well with your studies.

Yours sincerely,

Bob McMaster
Lead Nurse – Workforce & Education

Appendix 6. Patient Information Sheet

University of Chester

The Leeds Teaching Hospitals NHS
NHS Trust

An audit to test if the LTHT nutritional screening tool can identify haemodialysis patients at risk of malnutrition.

You are being invited to take part in a clinical audit. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take until your next dialysis session to read the following information and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information.

The following information can be read to you or left with you to read alone. Please discuss your preference with the researcher who approaches you, the sister on the unit (Sarah Simpson) or the researching dietitian (Kim Bowra). Thank you for your time.

What is the purpose of this study?

There are many guidelines that recommend the use of a nutritional screening tool to identify if patients receiving haemodialysis treatment are at risk of malnutrition. If a patient is highlighted to be at risk of malnutrition a referral to the dietitian for dietary assessment is then prompted.

Currently there are only general screening tools available, which cover a wide range of conditions but are limited in patients on haemodialysis.

The LTHT screening tool has been developed with information from the literature and from 4 previous small scale audits, which has involved previous patient and staff feedback.

The aim of this audit is to test whether the LTHT nutritional screening tool agrees with dietetic clinical judgement in identifying whether you are at risk of malnutrition or whether you are not at risk of malnutrition. The audit will also consider whether the tool is quick and easy to use.

Why have I been chosen?

You have been chosen because you have been receiving haemodialysis treatment for more than 3 months.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and asked to sign a consent form. You can nominate a carer to ask any questions and to take part on your behalf. Please discuss your preference with the person providing the tool or the sister on the unit (Sarah Simpson) or the researching dietitian (Kim Bowra).
If you decide to take part you are free to withdraw at any time and without giving a reason. A decision to withdraw or not to take part will not affect you in any way.

What will happen to me if I take part?

- You will be approached by a clinical support worker on dialysis to answer 4 questions from the LTHT screening tool; about your weight, eating, appetite and physical appearance. This will take about 10 minutes. A further 2 questions will then be completed by the staff member by using the computer system, to consider your weight and any recent weight loss. The LTHT screening tool is to be tested whilst you are on dialysis, as this is where the tool will be used eventually, just like other nursing care tools. You can have the curtain pulled around or you can complete the questions before or after dialysis if you prefer. Please indicate your preference.
- Some patients may be asked to complete the LTHT screening tool twice; once with the clinical support worker and once by yourself or with a nurse. This will be discussed with you at the beginning.
- You may also be asked to give some feedback on the LTHT screening tool by completing a feedback questionnaire, but this will be discussed with you. The questionnaire consists of 7 questions and will take about 15 minutes. The questionnaire can be completed by yourself alongside your carer, the nurse or clinical support worker, or on your own.

What will happen with my answers?

- The results of the LTHT screening tool will be compared with the dietetic clinical judgement results to see how accurate the screening tool is at identifying if you are at risk of malnutrition or if you are not at risk of malnutrition.

- Dietetic clinical judgement scores will be created by one dietitian, looking at notes of previous dietetic assessments and at the computer system, which is accessed as part of routine practice. If there is not enough information available, permission may be asked for the dietitian to gather this information from you in person.
- The feedback questionnaires will be collated to consider whether the screening tool needs any future improvements.

What if I am at risk of malnutrition?

- A referral to the dietitian for dietary assessment will be automatically generated if the dietetic clinical judgement method feels that you are at risk of malnutrition, regardless of the results of the LTHT screening tool, as the screening tool may not be accurate.
- If the LTHT screening tool results suggest that you are at risk of malnutrition, this will be checked against the dietetic clinical judgement results. As above, if you are deemed to be at risk of malnutrition by the dietetic clinical judgement method a referral will be automatically triggered. If however, the dietetic clinical judgement results suggest that you are not at clinical risk of malnutrition, a referral to the dietitian will not be generated.
- You can ask for the LTHT screening tool and the dietetic clinical judgement results. On request the dietitian will check the results of both and feedback to you within 10 working days.
- If you feel that a dietetic referral is required regardless of the audit results you can request to discuss this with the dietitian and a dietetic referral can then be considered together if necessary.
- If you are offered an appointment with the dietitian, you can accept or decline a referral to the dietitians.
- If you accept, the dietitian will then assess you within 2 weeks. The dietitian will update your doctor with any relevant information, as they would in routine practice.

What are the possible disadvantages and risks of taking part?

There are no known risks involved and it is hoped that any inconvenience to yourself will be limited. It is hoped that you will not find any of the questions to be of a sensitive nature or that any embarrassment is experienced. If you do not wish to answer any of the questions asked you can simply decline.

What are the possible advantages of being involved?

Your involvement will be of great worth for the development of an effective nutritional screening tool. The data will be analysed and depending on the results, the LTHT screening tool may be put into routine practice. The tool may need further modifying and auditing. If the tool is implemented it is hoped that future patient care will be further improved and that the tool will help you to become more aware of your risk of malnutrition.

Will my taking part in the study be kept confidential?

All information will be kept confidentially and data protection regulations will be followed for processing, storage and destruction. The information will be kept as per the NHS retention policy. Only staff working on the audit will have access to the data. There are no conflicts of interest.

What happens with the results of the study?

The results will be written up as part of an MSc project. Individuals who participate will not be identified in any subsequent report or publication.

Who is organising the research?

The research is conducted as part of a Masters qualification in Nutrition and Dietetics, within the Faculty of Life Sciences at the University of Chester. The study is organised by Kim Bowra, an MSc student. The Leeds Teaching Hospitals Trust is covering the majority of costs.

What if I have a question or a complaint?

There will be time for discussion and questions throughout the study. If there are any concerns that you may have you can contact the dietitian (Kim Bowra 0113 2065886) or the sister of the unit (Sarah Simpson). If you wish to complain to the university, please contact Professor Sarah Andrew, Dean of the Faculty of Life Sciences, University of Chester, Parkgate Road, Chester, CH1 4BJ, 01244 513055.

Thankyou for your interest.

Appendix 6. Consent form

University of Chester

The Leeds Teaching Hospitals NHS
NHS Trust

If you are happy with the information provided please sign below and agree your consent to take part.

Title of Project:
An audit to test if the LTHT nutritional screening tool can identify haemodialysis patients at risk of malnutrition.

Name of Researcher: Kim Bowra

Please initial box

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected. ☐

3. I agree to take part in the above study. ☐

4. I would like to nominate a carer Y/N

Carers name……. Carers signature…….

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Researcher	Date	Signature

Appendix 7. Sample size calculations

- **Sample size calculation used within this study**

The sample size calculation, taken from Jones (2004a, p 300) was specifically designed for the development of a NST, such as LST, using multivariate analysis, in which each variable is tested in order to consider the most effective tool.

> = 1000x number of risk variables/ percentage prevalence of malnutrition = patient required
>
> = 1000x 6 (varaibles in LST)/43% (based on previous small scale audits, see Appendix 1)
> n = 139 patients.

This is a realistic and feasible number, due to research funding obtained for the collation of data for the dependent variable.
Consider a 1% decline in participation and 0% dropout, based results from previous audit results (see Appendix 1). This was however a low figure and from clinical observation participants are frequently not available; admitted to hospital, receive transplants and pass away and therefore this sample number is the lowest minimum sample number to aim for.

- **Other sample size considerations**

Sensitivity and specificity power calculations were also considered (based on work by Jones, 2004b, p 315), as a fundamental consideration of testing NST accuracy, however these calculations produced figures that were not clinically feasible, n = 245 at a level of 80% sensitivity and specificity (as illustrated below). 80% is the figure set from literature appraisal and illustrated within Marian et al. (2013) and Weekes et al. (2004).

$$\mathbf{N_A = \frac{1.96^2 x 80\ (100-80)}{5^2}}$$

$$\mathbf{N = 245}$$

Calculation of reliability, as another key element of NST testing, also provided an unachievable sample number of n = 387 (Jones, 2004c, p 309), based on the unknown previous estimates available for other raters and Cantor's method.

N = 139 was a realistic number to achieve and allows for appropriate statistical analysis. Sensitivity, specificity and reliability could also be analysed within this number, as a fundamental part of analysis, albeit to a lesser extent.

Appendix 8- Training package for researchers

The LTHT Nutritional Screening Tool

Kim Bowra
Renal dietitian

1

Content

- Background
  - Why screen for malnutrition?
  - Previous audit results
- LTHT screening tool
- The study; recruitment, PIS, consent, the protocol
- LTHT Research guidance document; confidentiality, data protection and information governance
- Future implementation of the screening tool

2

Guidelines, Recommendations and Campaigns

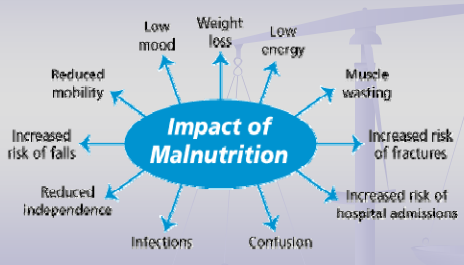
3

Definition of Malnutrition

- NICE guidance 2006 describes malnutrition as:-
  " a state in which a deficiency of nutrients such as energy, protein, vitamins and minerals causes measurable adverse effects on tissue composition, function or clinical outcome."
- The Renal Association (2010), quotes;
- NICE (2006) classification of a patient being at risk of malnutrition if they fall into any of these categories:
  - A body mass index (BMI) < 18.5 kg/m²
  - Unintentional weight loss >10% over the past 6 months
  - A BMI <20kg/m² and unintentional weight loss >5 % over the last 6 months.

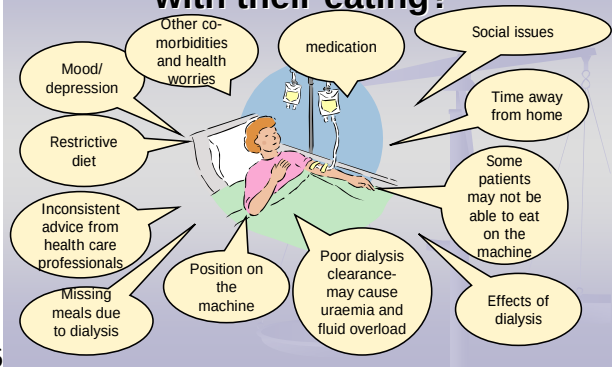
4

What is the impact of malnutrition?



5

Why may patients struggle with their eating?



6

Development of the renal screening tool

- 4 small scale audits to date
- Some patient and nursing involvement and feedback
- Renal dietetic team feedback
- Patient language group feedback
- Need to test in a bigger number and with the intended users

7

The LTHT Nutritional Screening tool for audit

8

The first step in the audit

- Ethical considerations
- Read and understand the principles of confidentiality, data protection and information governance- see the LTHT research guidance notes.
- Gaining patient consent- PIS and consent form
- Free to withdraw

9

Limiting bias

- 4 subjective questions to be answered first- with the patient
- Then 2 objective questions- at the computer
- Standard technique, *see the 5 step guide*.
- Ask the question, listen to the response, use their answer as a guide in completing the answers on the tool. Repeat the answer that you feel best suits what they have said so that they can clarify.
- If you are still unsure read all of the possible answers to the patient and they can decide
- If you remain unsure or feel this does not match your judgement then leave blank.

10

Questions to be asked

- Use your judgement alongside patient answers
- **A-** unintentional weight loss, amounts, time frames and medical changes
- **B and C-** intake and appetite are 2 different entities. Listen for amounts, frequency and timeframes.
- There may be no change, but this does not mean the intake is sufficient.
- **Possible warning signs are:**

Noticeable change in mood,

'My dentures are too loose'

'I've been feeling under the weather for a couple of weeks'

'I'm struggling with the cooking at the moment'

11

Question D

- Physical appearance may be challenging for the patient or user to identify.
- It is essential that this is considered jointly
- Patients that look slim, may not be malnourished.

Question: Who do you think is at risk of malnutrition?

Answer: Anyone could be at risk. It's not a matter of shape and size !

12

Some guidance






13

Question E and F

- Consider the most appropriate weight to use- TW, influenced by BCM results
- Is the weight history accurate? Or is it biased by previous fluid overload and therefore does not reflect flesh weight change?

14

The Nutritional care plan

- The importance of creating an average
- Documentation, see the data collection proforma
- Where appropriate dietetic referral may be indicated

15

Feedback

- Non-validated semi-structured questionnaires
- Audit analysis by the dietitian
- **Questions???**

16

Handout 1- The Leeds Teaching Hospitals NHS Trust, Research & Development Department 'DATA PROTECTION IN RESEARCH'.
Retrieved from;
http://www.leedsth.nhs.uk/fileadmin/Documents/Academic/Research/Documents/RESEARCH_PROPOSAL/DataProtectioninResearchGuidance.pdf

Appendix 8. Researcher standardised protocol - Handout 2

Discussion points

- **Introduction to the patient information sheet and consent sheet**
- The patient population are all deemed to be vulnerable due to their diagnosis and the hospital setting- A carer can be nominated by the patient to ask and answer questions.

- **Which objective measures will I need?**
- Patient height and weight measurements are a routine part of dialysis prescription, with patients wearing indoor clothing and without shoes.
- Height is measured on initiating HD and on clinical need, with the patient's feet flat on the base plate, with no shoes on and the body straight against the wall, a reading is taken as the head-plate touches the head. If the patient is unable to be heighted self-reported height is documented.
- Weights are taken before and after each dialysis session, using calibrated standard stand on scales and wheelchair scales. The pre and post HD weights, alongside 3 monthly bioelectrical impediance measures and clinical judgement, are reviewed by renal N/S at each HD session and inform the target weight.

- **The computer system provides these objective measures**
- Both measures are inputted to the computer system after each HD session, which calculates up-to-date BMI scores and percentage weight loss, using target weight.

- **What if the patient asks for their results?**
  The patient will not be given the results of the LTHT tool routinely, but they can ask for the results of the tool. Equally the patient can ask for the results of the clinical judgement method (the criterion measure).
  If the patient requests the results of either method, you need to explain the following;
  The results of the screening tool will be checked by a dietitian, as they may not be accurate and they will come and feedback the results from the screening tool that you completed, as well as the results from what the dietitian has assessed. This will happen within 10 working days.

- **What happens then? What if the patient is highlighted to be at risk of malnutrition?**
  Only if the patient is highlighted to be at risk of malnutrition, based on the criterion method of dietetic clinical judgement, they will be routinely offered an appointment for a dietetic assessment, where support can be provided. The assessment will be done independently of the lead researching dietitian.
  If the patient is not deemed to be at risk by the criterion method, this will be discussed with them by the independent dietitian and a dietetic assessment will only be offered if the patient requests this.
  If the participant does not ask for the results of the tool but they are found to be at risk of malnutrition by the clinical judgement method the independent dietitian will offer the patient an appointment for dietetic assessment.
  The proforma in use to highlight this will be shown to you.

- **The researcher protocol- see Handout 3**

- **Data proformas to be used and by who- show examples**

Appendix 8. Researcher standardised protocol continued (Handout 3)-
5 step guide for completing the nutritional screening tool

1. It is <u>essential</u> to gain patient consent before completing the screening tool

-In order to gain consent the patient needs to understand what they are consenting to
Ie/ A number of questions asking about their nutritional status, if this shows they are at risk of malnutrition then they will be offered a referral to the dietitian
- Circle consent Y for yes if the patient agrees to complete the tool
- If the patient does not consent. Circle N for No and plan to re-screen in 3 months
- Please complete your position, name and date to show who has gained consent from the patient

2. The nutritional screening tool has 4 questions that you can ask the patient. Where possible you need to ask the patient questions A to D

- Ask the question outlined and listen to their response
- Using their answers as a guide circle the score appropriate to their answer. Use their answer alongside your clinical judgement to decide on this score.
- Read the answer to the patient that you feel fits with what the patient has said in order to clarify their meaning and to ensure the appropriate score is given
-If the answer they provide falls between two of the answers outlined or you are unsure which score to give read all of the answers, from 1 to 4 to the patient and then you can agree the appropriate score

3. There may be some questions which you feel cannot be asked- as the answers are unknown, unavailable or you feel you are not able to score due to lack of clarity from the patient. It **is important to answer as many questions as you can to make the score as appropriate as possible. However a wrong answer will affect the results and so when unsure leave blank.**

Consider the illustrations below;

- <u>Question A and E- You may not know the extent of the recent 'weight loss' of the patient;</u>
  - If they have come from another hospital and so we have no history available
  - If the patient does not know or cannot give an accurate recent weight history
  - If the patient is known to have been very fluid overloaded previously and so you feel the weights available do not accurately consider flesh weight
- <u>Question D- You may find it difficult to grade a patients physical appearance.</u>
  - Those patients that appear as slim or very slim may have been this way for a long time and are actually not malnourished
  - Likewise in those that are very overweight any muscle and fat loss maybe be somewhat hidden
  - It is very important to ask the patient how they feel and using their answer consider alongside your clinical judgement

4. When considering BMI and weight change we need to choose the most reliable weight available

-The most accurate weight is the target weight, informed by a BCM test
- If you are concerned that a BCM has not been completed in a timely way, this can be requested
- On considering the appropriate score for weight change we must only consider unintentional weight loss and so it is important to emphasise this to the patient as per question A

5. For the scores to make sense we need to create an average. This is done adding the scores together and dividing the total by the number of questions asked

- Consider a patient who does not speak English for example, only questions D, E & F can be answered
- To generate an average, the answered questions need to have their scores added together. In this example scores of 2+3+4 were generated = 9 as a total score. 9 (total score) divided by 3 (questions) provides the average score of 3

<u>The score is important so that the referrals can be triaged appropriately and priority patients noted. The action required should match your clinical judgement. If a referral is required remember the patient needs to consent to this process and then a referral form can be faxed to the dietetic department. There may be other reasons for a dietetic referral; diabetes, renal dietary advice, weight management for example.</u>

Appendix 8. Methodological detail linking to Section 3.32 and Figure 3.1

Study procedure detail.

Those in **step 1a** and those in **step 3** formed part of the reliability testing, whereby both sets of results were then independently compared to the results generated by the CSW, at a later stage.

The N/S identified those patients that were known to be able to self-complete for **step 1a**, as 14 consecutive patients on the computer report (consistent with Cawood et al., 2012), albeit one patient declined. The N/S did not screen any of the self-completion patient group and so this helped to eliminate procedural bias. All of the patients in **step 1a** completed the subjective questions (A to D) and then a questionnaire. The objective questions were completed by the independent dietitian.

Within 7 days, the CSW screened the patient in **step 1b**. All patients in **step 2** were screened by the CSW and every 9th patient on the list completed a semi-structured questionnaire(n = 16). The CSW completed a questionnaire biweekly (n = 4), based on their experience in using the LST.

The CSW, **in step 3**, identified 4 patients per week, as every 7th patient on the computer report, for the N/S to screen within 7 days of CSW screening (to a total of 14). The nurse completed the NS and then completed a semi-structured questionnaire (Appendix 4).

In **step 4**, the researching dietitian was instructed by the CSW to complete the criterion measure, whereby on a weekly basis a list of patient numbers was provided, for those who had consented and completed the LST (in step 1b, 2 and 3). Creating the criterion measure after the independent variable, may limit bias as the patient may be less aware of their nutritional status at this time than those that are being assessed by the dietitian.

Data collection

An independent dietitian located results from each step and transfered to one proforma. None of the patients asked for their results and so the independent dietitian was not required to approach the patients for this purpose. Data was not compared by the researching dietitian until the all data had been collected.

Appendix 9. Non-Validated questionnaires

Clinical support worker and nurse semi-structured questionnaire.

Date……

Thank you for using the nutritional screening tool with the patients
Please consider the following 6 questions, based on your experience of using the nutritional screening tool; the way the questions were asked, the questions themselves and any thoughts or feelings you may have which we can use to improve the tool.
Please circle the answers below and provide comments and suggestions where indicated.
Name ……

Questions

1. Do you feel that the reason for using the screening tool is clearly understood by the patients?
Yes/No and suggestions

2. Do you feel the patients clearly understood the **questions** asked?
Yes/No and suggestions

3. Do you feel the suggested **answers** captured the patients answers?
Yes/No and suggestions

4. Do you have any comments with regards to appearance of the tool?
Yes/No and suggestions

5. Do you have any comments with regards to the practicalities of using the tool?
Yes/No and suggestions

6. Further comments

Thank you for completing this feedback.

Appendix 9. Patient questionnaire

Date…….

Thank you for completing the nutritional screening tool
We would now like to ask you if you have any feedback about the tool; the way the questions were asked, the questions themselves and any thoughts or feelings you may have which we can use to improve the tool.
Please complete your name below or equally you can complete the feedback without leaving your name.

Name ……

There are 7 questions about the nutritional screening tool listed. You can complete this whilst on dialysis, after dialysis or at home. You can complete this by yourself, with a carer, a nurse or clinical support worker reading and writing your answers down for you.

Please advise which is most suitable to you.

Questions

1. Do you feel that the reason for using the screening tool has been clearly explained to you?
Yes/No and suggestions

2. Do you feel the **questions** asked were clear in their meaning?
Yes/No and suggestions

3. Do you feel the **answers** available captured what you wanted to say?
Yes/No and suggestions

4. If you completed the tool yourself, do you have any comments with about the appearance of the tool?
Yes/No and suggestions

5. Do you feel that the screening tool results agree with how you feel about your risk of malnutrition?
Yes/No and suggestions

6. Do you have any comments with how the tool was used in practice? Yes/No and suggestions

7. Further comments

Thank you for completing this feedback. **We welcome any positive comments and any suggested improvements. The information you have provided will be used to better the nutritional screening tool so that in the future we hope to use a tool that has been developed alongside patients receiving haemodialysis treatment.**

Appendix 10. Statistical testing, links with section 4.1

Correlation of risk variables with risk of malnutrition (links to 4.2)

Correlations

			Renal	PRDText	CVD	smoker	postWt	BMI	chnange
Spearman's rho	MAL	Correlation Coefficient	-.178*	-.083	.114	.169	-.299**	-.329**	.658**
		Sig. (2-tailed)	.050	.347	.225	.096	.000	.000	.000
		N	122	132	116	98	140	140	140
	age	Correlation Coefficient	-.090	-.090	.398**	-.070	.101	.087	.118
		Sig. (2-tailed)	.325	.304	.000	.495	.233	.308	.174
		N	122	132	116	98	140	140	140
	gender	Correlation Coefficient	.138	.027	-.088	-.008	-.269**	.051	.135
		Sig. (2-tailed)	.128	.762	.347	.941	.001	.549	.113
		N	122	132	116	98	140	140	140
	ethnicity	Correlation Coefficient	.068	.035	-.100	-.159	-.073	-.067	.049
		Sig. (2-tailed)	.459	.691	.283	.118	.394	.431	.565
		N	122	132	116	98	140	140	140
	DoFRRT	Correlation Coefficient	.037	-.133	-.038	-.058	-.183*	-.132	.033
		Sig. (2-tailed)	.687	.129	.687	.572	.031	.121	.696
		N	122	132	116	98	140	140	140
	Renal	Correlation Coefficient	1.000	-.060	-.008	-.058	-.012	.041	-.107
		Sig. (2-tailed)	.	.516	.935	.598	.899	.655	.240
		N	122	118	103	85	122	122	122
	PRDText	Correlation Coefficient	-.060	1.000	-.140	.077	.028	.032	.035
		Sig. (2-tailed)	.516	.	.134	.454	.754	.717	.690
		N	118	132	116	97	132	132	132
	CVD	Correlation Coefficient	-.008	-.140	1.000	.009	.027	-.026	.018
		Sig. (2-tailed)	.935	.134	.	.933	.771	.784	.852
		N	103	116	116	97	116	116	116
	smoker	Correlation Coefficient	-.058	.077	.009	1.000	-.124	-.171	.063
		Sig. (2-tailed)	.598	.454	.933	.	.226	.093	.536
		N	85	97	97	98	98	98	98
	postWt	Correlation Coefficient	-.012	.028	.027	-.124	1.000	.872**	-.264**

Multivariate analysis- Multiple regression (links with 4.4.4)

Model Summary[e]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.781[a]	.611	.607	.556
2	.845[b]	.715	.710	.478
3	.893[c]	.797	.792	.405
4	.903[d]	.815	.809	.388

a. Predictors: (Constant), F

b. Predictors: (Constant), F, E

c. Predictors: (Constant), F, E, B

d. Predictors: (Constant), F, E, B, D

e. Dependent Variable: Dietitian

the Stepwise analysis shows model 4 has highest R value

Multiple regression continued

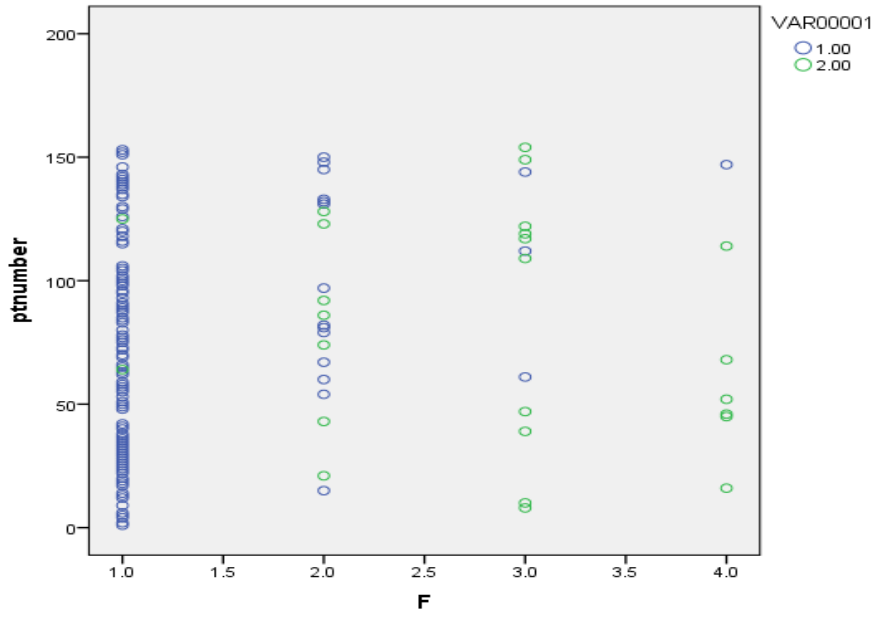
Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	.551	.101		5.427	.000	.350	.751					
	F	.772	.059	.758	13.081	.000	.655	.889	.758	.758	.758	1.000	1.000
2	(Constant)	.162	.109		1.482	.141	-.054	.379					
	F	.660	.055	.647	11.970	.000	.551	.769	.758	.729	.611	.890	1.124
	E	.383	.062	.332	6.138	.000	.260	.507	.547	.480	.313	.890	1.124
3	(Constant)	-.049	.097		-.508	.612	-.242	.143					
	F	.407	.058	.399	6.963	.000	.291	.522	.758	.529	.300	.566	1.768
	E	.387	.053	.336	7.343	.000	.283	.492	.547	.549	.317	.890	1.124
	D	.365	.051	.396	7.169	.000	.264	.465	.712	.540	.309	.610	1.638
4	(Constant)	-.228	.101		-2.250	.026	-.429	-.027					
	F	.425	.055	.417	7.701	.000	.316	.535	.758	.569	.313	.562	1.780
	E	.396	.050	.343	7.951	.000	.297	.494	.547	.581	.323	.888	1.126
	D	.258	.055	.280	4.739	.000	.150	.366	.712	.392	.193	.472	2.119
	B	.207	.050	.196	4.097	.000	.107	.306	.469	.345	.166	.719	1.391

a. Dependent Variable: Dietitian

Scatter diagrams for objective data (links to 4.4.4)

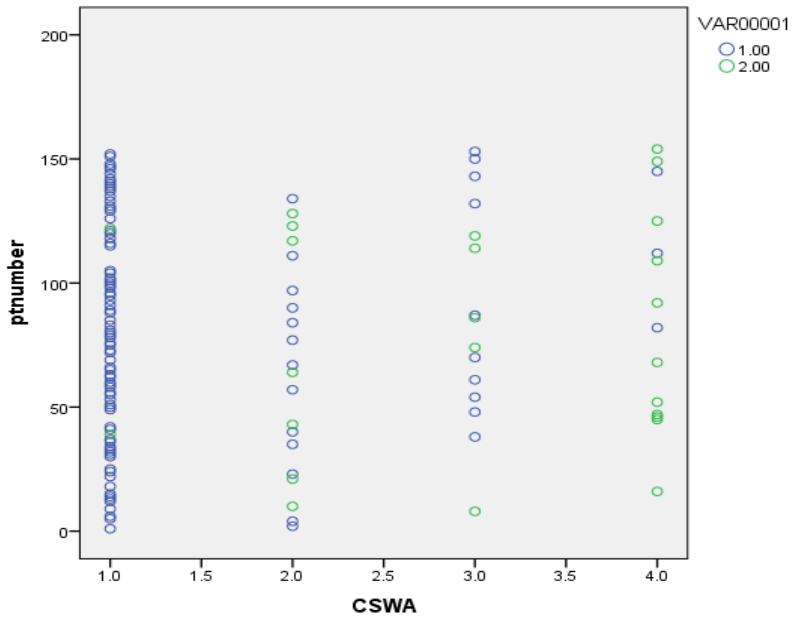
Note Green = at risk and blue = not at risk



Weight loss (variable F)

Agrees with anticipated results in that those at risk (in green) should be in position 3 and 4 on the X axis and those in blue in position 1 or 2.

Scatter diagrams for subjective variables



Subjective weight change (variable A)

It would be anticipated that those at risk (green) would be closer to 3 and 4 and blue (not at risk)

would be in position 1 and 2 of the X axis.

Eligible participants that failed to complete (links with 5.3)

Reasons and numbers of attrition	Age		BMI		Weight change		Diabetes		More than 1 Co-morbidity *	
	Median (years)	range	Median (Kg/m^2)	range	Median (%)	range	Yes (n)	No (n)	Yes (n)	No (n)
In hospital (n = 3)	81	70.4-89.3	27.1	19.6-29.9	1.5	0-2	2/3	1/3	3/3	0/3
Received a transplant (n = 3)	45.9	29.4-53.8	28	23.6-33.9	0	0-1.2	0/3	3/3	0/3	3/3
RIP (n = 7)	74.1	13.1	22.7	3.3	1.2	2.2	1/3	2/3	1/3	1/3
Declined (n = 3)	76	48.7-89.3	22.05	19.6-27.2	0.7	0-5.3	2/8	6/8	5/8	3/8
Total (n = 16)	71.1	29.2-89.3	28.5	19.6-35.5	0	0-5.3	5/16	11/16	9/16	7/16

*Note.**including emphysema, diabetes, malignancy and liver disease

Characteristics of those that did not complete remained similar to those that completed (Table 3.3).